PlasmaKinetic™ SuperPulse Generator

USER MANUAL

Manufactured for:
Gyrus ACMI,
136 Turnpike Road
Southborough
MA 01772-2104
USA

EC REP
Gyrus Medical Ltd
St Mellons
Cardiff
CF3 0LT
United Kingdom

CE 0344

Rx only

Customer Service USA:
Customer Service: 1-888-524-7266
Technical Service: 1-800-621-3739
www.gyrusacmi.com

REF 744000

Part Number: 114020-LB
2011-02

This user manual will familiarize you with the controls and output functions available from your Gyrus ACMI SuprePulse Generator and instruct you on its proper use.

Copyright Gyrus Medical, Ltd. 2010. All rights reserved. No part of this publication may be reproduced, transmitted, transcribed, stored in retrieval systems, or translated into any language or computer language, in any form, or by any means: electronic, mechanical, magnetic, optical, or otherwise, without the prior written permission of Gyrus ACMI.

Patents This product may be covered by one or more of the following US patents:
5,944,715; 6,004,319; 6,013,076; 6,015,406; 6,045,549; 6,056,746; 6,074,386, 6,090,106, 6,093,186; 6,152,143; 6,131,579; 6,179,803; 6,210,355; 6,210,405; 6,228,081; 6,234,178; 6,261,286; 6,293,942; 6,303,134; 6,364,877; 6,416,491; 6,416,509; 6,482,202; 6,517,535; 6,371,926; 6,682,501, 6,893,435,6,984,231, 7,214,224, 7,211,081, 7,195,627.
Associated Patents are in place in other countries

OVERVIEW OF THE GYRUS ACMI SUPERPULSE GENERATOR

The Gyrus ACMI SuperPulse Generator forms a versatile platform for Urology and General surgical use.

Ensure that the contents of this User Manual are read and understood before proceeding to use the Gyrus ACMI SuperPulse Generator.

TABLE OF CONTENTS

SECTION	PART		PAGE
1		**INTRODUCTION**	
	1A	Overview of the Superpulse System	1-1
	1B	Comparison with Conventional Surgery	1-1
	1C	Indications for Use	1-2
	1D	Contraindications for Use	1-2
	1E	System Description	1-2
2		**PATIENT AND OPERATING ROOM SAFETY**	
	2A	General	2-1
	2B.	Servicing/Equipment Disposal	2-2
	2C	Fire/Explosion	2-3
	2D	Before Surgery	2-3
	2E	During Surgery	2-4
	2F	After Surgery	2-6
	2G	EMC Classification	2-6
3		**INSTALLATION**	
	3A	Responsibility of the Manufacturer	3-1
	3B	SuperPulse Generator Power Requirements	3-1
	3C	Grounding of the SuperPulse Generator	3-1
	3D.	Routine Maintenance of the SuperPulse Generator	3-1
4		**GENERAL INFORMATION**	
	4A	SuperPulse Generator Indicators and Displays	4-1
	4B	Output Mode Selection Power Controls	4-3
	4C	Olympus TURis Mode	4-5
	4D	SuperPulse Generator Indicators, Set-up and Malfunction Displays	4-7
	4E	Changing the Display Language	4-10
	4F	Enabling Additional Instruments via a PIN code	4-11
5		**BEFORE SURGERY**	
	5A	Power up the SuperPulse Generator	5-1
	5B	Select the Appropriate PK/SP Instrument(s) for the Procedure	5-2
	5C	Steam Sterilise the PK Connector Cable, PlasmaKinetic™ Resectoscope or appropriate urological endoscope	5-4
	5D	Connect the PK Connector Cable	5-4
	5E	Prepare the PlasmaKinetic™ Resectoscope or urological endoscope	5-4
	5F	Attach PlasmaKinetic™ Instrument to the PK Connector Cable	5-8
6		**DURING SURGERY**	
	6A	Accessories	6-1
	6B	Recommendations during Surgery	6-1
7		**TECHNIQUES TO OPTIMIZE PERFORMANCE**	7-1
8		**AFTER SURGERY**	
	8A	Following Surgery Involving PlasmaKinetic™ Resectoscope Instruments	8-1
	8B	Following Surgery Involving PlasmaKinetic™ Cystoscope Instruments	8-1
	8C	Following all Surgery Involving the Superpulse Endourology System	8-2
9		**OPERATING ROOM TROUBLESHOOTING**	9-1
10		**PERFORMANCE SPECIFICATIONS**	10-1
11		**ERROR AND FAULT CODES**	11-1
12		**EXPLANATION OF SYMBOLS**	12-1
13		**PERIODIC EQUIPMENT SAFETY CHECKS**	13-1
14		**EMC TABLES**	14-1
15		**LIMITED WARRANTY**	15-1

SECTION 1 INTRODUCTION

Gyrus Medical Ltd, Gyrus Medical Inc and Gyrus ACMI Inc are referred to as Gyrus ACMI in this user manual.

This user's manual will familiarise you with the controls and output functions available from your SuperPulse System and instruct you on its proper use.

1A. Overview of the SuperPulse System

An endoscope is an instrument routinely employed to visualise and access the interior of various body cavities for the purposes of both diagnostic and surgical procedures. The endoscope is inserted through a natural body opening, such as the cervical canal or urethra. The instrument commonly includes one or more integral working channels for the passage of surgical instruments, as well as conduits for the passage of gas or liquid required to distend the body cavity. Commonly referred to as 'underwater surgery', liquid distension is usually the preferred method in urological endoscopy.

Electro surgery is a familiar tool widely employed in urological endoscopy to perform transurethral prostatectomy (TURP), resection of bladder tumours and cystodiathermy. Based on similar principles, the PlasmaKinetic™ technology exploits the electrical conductive properties of fluid used to distend the operative site, requiring the standard non-electrolyte irrigation fluids used during conventional TURP to be replaced by normal saline. By adjusting power in microseconds two tissue effect modes can be produced. In the first mode, an ionised plasma corona is created over the active zone of a tissue treatment electrode. Tissue entering the intense kinetic energy of the corona is instantly reduced to its constituent elements and simply washed away in the irrigation fluid. The low thermal mass of the plasma prevents collateral tissue damage adjacent to the application site. In the second mode, rapid, predictable and controlled elevations in tissue temperature can be produced to ablate tissue or seal blood vessels.

The SuperPulse mode of operation enables very rapid formation of the plasma enabling easier and more rapid resection of tissue.

1B. Comparison with Conventional Electrosurgery

Conventional bipolar electrosurgery requires that both 'poles' of the electrode contact tissue to complete the electrical circuit and produce a tissue effect. Typically, these electrodes do not operate effectively while immersed in a conductive irrigating solution such as normal saline. The Gyrus ACMI SuperPulse Endourology System utilises the fact that saline is electrically conductive to control an ionised plasma around the active tip when electrosurgical current is applied. Essential to this design is the proximity of the return electrode to the active electrode in an Axipolar™ configuration. The fact that the two poles of the circuit are only a few millimetres apart means that current flows only through the irrigant or through the tissue to be vaporised. This localised current flow preserves the recognised safety features of conventional bipolar electrosurgery. Similarly, this arrangement avoids many of the problems commonly encountered when using bipolar electrosurgery: orientation of the electrode to tissue, visualisation of the working tip, tissue sticking and limited power delivery.

The intense concentration of electrosurgical energy delivered by the technology offers instantaneous vaporisation of tissue. This effect can be achieved with monopolar electrosurgery but at very high power levels and only in the presence of a non-electrolyte irrigating solution, both aspects of which have recognised complications and safety concerns. Furthermore, the deep tissue heating of monopolar arrangements which occurs during tissue vaporisation causes a progressive deterioration in efficiency over the period of the procedure. The PlasmaKinetic™ technology overcomes this problem and provides a repeatable tissue effect throughout the procedure. In order for the system to produce this effect, the SuperPulse Generator has integral feedback systems to both initiate and sustain the plasma corona around the active electrode.

The instruments can only operate within a saline medium. The size of the working tip geometry determines the amount of power needed to ensure optimal performance. To simplify set-up the

SuperPulse Generator will automatically select a default power and mode setting according to the instrument type. Power and mode adjustments can be performed by the front panel buttons with the selected output shown on the user display.
Instruments are supplied in a sterile, single use format and connect to the SuperPulse Generator via a limited re-use connector cable. Activation of the electrosurgical current is by means of a footswitch, attached via the back panel. Activation is inhibited by safety circuitry until both instrument and connector cable have been properly coupled to the SuperPulse Generator. An audible alarm will sound whenever electrosurgical energy is being output. Diagnostic circuits within the SuperPulse Generator continuously monitor system performance. Any detected faults are indicated as symbols on the user display in conjunction with the illumination of the front panel warning symbol.

1 C. Indication for Use

The Gyrus ACMI PK Superpulse System is intended for use for ablation, removal, resection and coagulation of soft tissue and where associated haemostasis is required in open, endoscopic and laparoscopic surgical procedures.
The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

1D. Contraindications for Use

The use of this device is contraindicated in patients with the following conditions:

- Carcinoma of the bladder or prostate without tissue diagnosis.
- Patients with urinary tract infection.
- Patients with incipient renal failure.

It is advisable to monitor the input and output volumes of the irrigation fluid in all patients but especially those with cardiovascular insufficiency or poor renal function.

Patients with Pacemakers
Use with caution in the presence of internal or external pacemakers. Interference from an electrosurgical current can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital Cardiology Department.

1E. System Description

The SuperPulse Endourology System (figure 1.1) is designed for resectoscopic and endoscopic urological procedures performed on the lower urinary tract. A typical system comprises the following items:

- A SuperPulse Generator (Model 744000)
- A Gyrus ACMI Footswitch (Model 744010)
- Suitable connector cable to connect to the Gyrus or Olympus Resectoscope.
- Use only approved accessories - Contact your sales representative.

When used with a PlasmaKinetic™ Resectoscope

- A suitable Gyrus ACMI Urology Electrode (e.g. PK Plasma Sect, PK SuperSect, Superloop and PK Button) (see Fig 1.2)
-

When used with a suitable urological endoscope (e.g. Cystoscope)

- A PK Plasma-Cise™ or PK Plasma Cut™ instrument (see Fig 1.3)

When used with an approved Resectoscope

- Olympus Electrodes – Compatible with the Gyrus ACMI SuperPulse System.
  Supplied with connector cable

Typical Resectoscope Components

Working Element Active
- Or -
Working Element Passive
Telescope
Inner sheath
Outer sheath
- Or -
Outer sheath rotatable

Standard Obturator
Olympus Light Guide Adapter
Visual Obturator
Ellik Evacuator Adapter
Continuous Flow Sheath
Resectoscope Sheath (24 Fr. Intermittent Sheath)

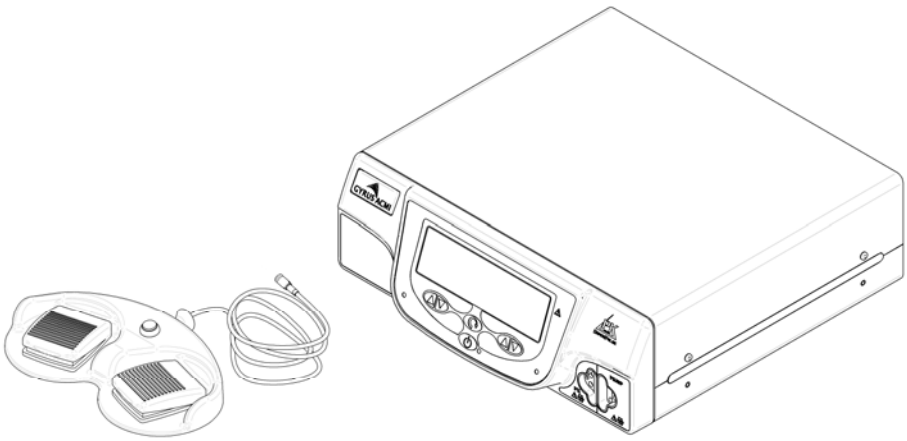


Fig 1.1 Example System

The instruments are available in three basic forms.
The resectoscope Instruments (figure 1.2) are designed to be used in conjunction with the PlasmaKinetic™ resectoscope which is designed to accept the instrument which is connected directly to the connector cable rather than to the resectoscope. Typical use of these types of instruments would be in the surgical treatment of benign prostatic hyperplasia.

The cystoscope Instruments (figure 1.3) are intended for insertion through the working channel of any standard, commercially available urological endoscope with a 5Fr. or larger working channel. Typical use of these instruments would be for the desiccation and vaporisation of recurrent bladder tumours.

In addition certain Olympus TURis instruments can also be used (see Fig 1.5)

Instruments are designed to provide either vaporisation or desiccation of tissue, using the yellow and blue pedals respectively, of the dual footswitch. The vaporization is achieved with “SuperPulse” (SP) mode or “PlasmaKinetic” (PK) modes, depending on instrument type. Desiccation uses the Desiccated (DES) mode. A third mode is also available, the ThermoKinetic™ mode (TS or T).
This mode provides either modulated “SuperPulse” (TS) or a blend of PlasmaKinetic™ and Desiccate (T) electrosurgical currents and offers a reduced vaporisation effect but with enhanced hemostatic effect.

.

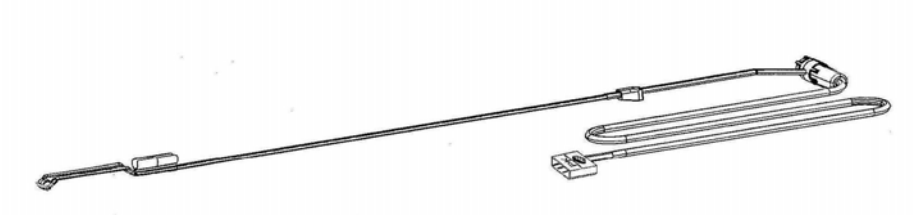


Fig 1.2
Example of Gyrus ACMI Resectoscopic Instruments – For use with Reusable Cable

Fig 1.3
Example of Gyrus ACMI Resectoscopic instruments with Disposable Cable

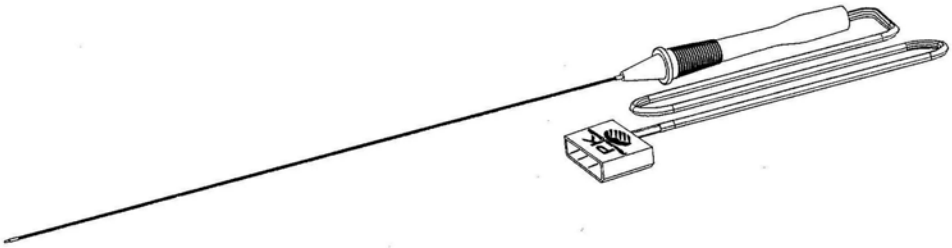


Fig 1.4
Example of Gyrus ACMI Cystoscopic Instruments.

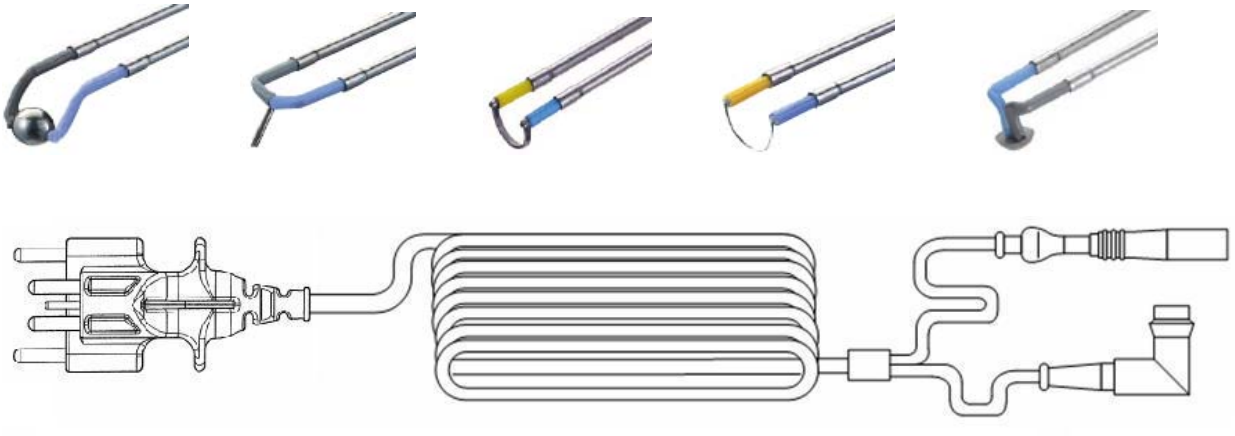


Fig 1.5
Examples of Olympus Resectoscopic Instruments

A specific TURis mode is only available when a TURis cable is connected to the SuperPulse Generator.

SECTION 2 PATIENT AND OPERATING ROOM SAFETY

For the purposes of safety procedures and despite the absence of a conventional return pad, the Gyrus ACMI SuperPulse Endourology System should still be treated as a high power electrosurgical device.

The safe and effective use of electrosurgery depends to a large degree upon factors and variables solely under the control of the operator. There is no substitute for good surgical technique and properly trained operating room staff. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, and understood, and followed.

Electrosurgery has been employed safely in numerous procedures. Before starting any surgical procedure the physician should be familiar with the medical literature, complications and hazards of electrosurgery in that procedure.

2A. General

WARNING Hazardous Electrical Output: This equipment is for use only by qualified personnel. Use only approved accessories.

WARNING Do not use a monopolar generator/accessories simultaneously with the SP generator. Activation of a monopolar generator/accessories may cause interference with the SP generator resulting in user message changes on the display. Before proceeding with surgery, confirm proper power settings are displayed on the generator. Ensure the appropriate output setting is enabled for the desired surgical outcome.

WARNING Direct contact between activated monopolar accessories and SP generator connected accessories could damage the SP generator. If such damage is suspected, the SP generator should be returned to Gyrus ACMI for inspection.

WARNING Use with caution in the presence of internal or external pacemakers. Interference from an electrosurgical current can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital Cardiology Department.

WARNING Do not use electrosurgical equipment unless properly trained in its use in the specific procedure intended.

WARNING Electrodes and probes used with monitoring, stimulation, and imaging devices (or similar equipment) can provide a path for high frequency current even if they are isolated. To reduce the risk of an inadvertent burn at the electrode site, place the electrode and / or probe as far away as possible from the electrosurgical site.

WARNING **ONLY USE 0.9% w/w SALINE FOR IRRIGATION**.
Performance will be suppressed by use of other irrigating solutions such as Glycine, Sorbitol, Dextrose, Mannitol or other solutions containing non-physiological concentrations of electrolyte

CAUTION If two accessories are connected to the SP generator, ensure the appropriate accessory is selected prior to activation. Activation of the unintended accessory could cause unintentional tissue effect.

CAUTION Do not activate electrodes while in contact with other instruments as unintended tissue effect may occur.

CAUTION Do not activate the generator in an open circuit condition, this may result in excessive heating of the irrigation medium. To reduce the risk of unintended effects, activate the generator only when the active accessory is near or touching the target tissue.

CAUTION Do not apply excessive pressure to the accessory tip during use as damage may result.

CAUTION Use the lowest appropriate power setting to achieve the desired effect.

CAUTION This equipment is capable of producing a physiological effect.

CAUTION Read the instructions, cautions, and warnings provided with Gyrus ACMI SuperPulse Endourology System accessories before use. This device is an integral system; only use approved accessories with the Superpulse Generator. Your sales representative can advise which accessories are available and approved for use with the Superpulse System.

CAUTION If possible, avoid the use of needle style instruments for any physiological monitoring equipment that may be connected to the patient during electrosurgery.

CAUTION Where practical; only use monitoring equipment that incorporates high frequency current limiting devices during electrosurgical procedures.

CAUTION The connector cable should be positioned so that it avoids contact with the patient and any other leads.

CAUTION Studies have shown that electrosurgical smoke generated during electrosurgical procedures can be potentially harmful to surgical personnel.

CAUTION Examine all accessories and connections to the electrosurgical SuperPulse Generator before use. Improper connection may result in arcs and sparks, accessory malfunction, or unintended surgical effects.

CAUTION Do not insert fingers or objects other than the correct cables into the socket. Only activate the footswitch with an instrument attached.

WARNING The PK or SP system has not been cleared for tubal sterilization. Do not use this system for these procedures.

CAUTION The Gyrus ACMI SuperPulse Endourology System should only be activated with the working tip of the instrument completely immersed in 0.9% w/v 150mMol/l sodium chloride solution. For convenience, this will be referred to within the remainder of this manual as normal saline.

2B. Servicing/Equipment Disposal

CAUTION Electrical Shock Hazard: Do not tamper with the SuperPulse Generator housing or attempt to remove the control panel. Refer to authorised personnel for service.

NOTE
1. There are no user serviceable parts within the product.
2. For maintenance of the SuperPulse Generator refer to the recommended periodic equipment safety checks in Section 13.

CAUTION The SuperPulse Generator contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable policies relating to obsolete electronic equipment.

CAUTION Dispose of any system accessories according to normal institution practice relating to disposal of biologically contaminated items.

2C. Fire/Explosion

DANGER Explosion Hazard: Do not use in the presence of flammable anaesthetics.

WARNING Explosion Hazard: The following substances will contribute to increased fire and explosion hazards in the operating room:

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives should be allowed to evaporate before the application of electrosurgery. There is a risk of pooling of flammable solutions under the patient or in body cavities during endoscopic surgery. Any fluid pooled in these areas should be mopped up before electrosurgery is used.
- Endogenous gases.
- Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen enriched atmospheres.
- Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of electrosurgical equipment.

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times.

WARNING Fire/Explosion Hazard: Verify that all oxygen circuit connections are leak free before and during use of electrosurgery. When using electrosurgery in the same room with any of the above substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is being performed.

2D. Before Surgery

Active Accessories

WARNING Electric Shock Hazard: Do not connect wet accessories to the SuperPulse Generator.

WARNING Electric Shock Hazard: Ensure that all accessories are correctly connected and that no metal is exposed.

WARNING Do not attempt to re-use instruments labelled for Single Use Only. Heat or chemical Sterilization may render the instrument mechanically or electrically unsafe

CAUTION Read the instructions, warnings and cautions provided with the active accessories before using.

CAUTION Accessories labelled re-usable must only be processed according to the recommended procedure and, where appropriate, recycled the specified number of times.

CAUTION Use default power levels to test an accessory.

CAUTION Use only approved accessories supplied for use with this product. Product damage or accessory failure may otherwise result during use. Your sales contact can advise what accessories are available.

CAUTION Always inspect the system accessories for damage prior to use. In particular, check the cables of any re-usable accessory for possible insulation damage.

SuperPulse Generator

WARNING Electric Shock Hazard. Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.

WARNING Fire Hazard. Do not use extension cords.

CAUTION Provide as much distance as possible between the SuperPulse Generator and other electronic equipment (such as monitors) as an activated SuperPulse Generator may cause interference with them.

CAUTION Non-function of the SuperPulse Generator may cause interruption of surgery. Ensure that all installation procedures are followed and that all connectors are correctly inserted before use. A backup generator should be available for use.

CAUTION Do not stack equipment on top of the generator or place the generator on top of electrical equipment.

CAUTION Do not set the activation tone down to an inaudible level. The activation tone alerts surgical personnel when an accessory is active.

2E. During Surgery

Contact With Metal Objects

WARNING Use extreme caution when using electrosurgery in close proximity to or in direct contact with any metal objects. The working channel and operating sheaths of most rigid endoscopes are metal. Do not activate the instrument while any portion of the instrument tip is within the sheath or working channel, or in contact with another metal object. Localised heating of the instrument and the adjacent metal object or working channel may result in damage to the contacting endoscope, and/or instrument tip.

WARNING While using electrosurgery during a surgical procedure, the patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.). If this is not possible, use extreme caution to maximise patient safety. The use of antistatic sheeting is recommended for this purpose.

WARNING Risk of injury to patient: Thermal cell damage can occur when using preheated irrigation fluid. Always make sure that the temperature of the irrigation fluid does not rise above body temperature (37 °C/99 °F).

WARNING Risk of injury to patient: Localised excessive heating of the irrigation fluid can be caused by HF current. Always make sure to use a sufficient flow rate (minimum 1 litre/5 min).

SuperPulse Generator Power Settings

WARNING Confirm proper power settings are displayed on the SuperPulse Generator before proceeding with surgery. Ensure the appropriate output setting is enabled for the desired surgical outcome before activating the instrument and ensure that activation is for the minimum time to achieve the desired surgical effect.

CAUTION Upon reconnection of an instrument to the electrosurgical SuperPulse Generator, or after navigation using the Mode / Menu button, the power settings for cutting and coagulation may be changed from previously selected values.

WARNING Do not simultaneously activate the SuperPulse Generator whilst activating with any other electrosurgical equipment (on the same patient). Failure to observe this may result in the attached instrument being unrecognized by the system.

CAUTION Failure of the HF SURGICAL EQUIPMENT could result in an unintended increase or decrease in output power.

CAUTION Use caution when overriding the default power settings.

CAUTION Should a power supply interruption occur, the generator will revert to its Standby state. The user should press the Standby / On button to restart the generator and then press the Mode / Menu button to accept the default instrument settings.

Instrument Accessories

WARNING When not in use, place active instruments in a clean, dry, non-conductive, and highly visible area not in contact with the patient. Inadvertent activation while in contact with the patient may result in burns.

WARNING Do not wrap accessory cords around metal objects. This may induce currents that could lead to injury to the patient or surgical personnel.

WARNING Fire Hazard: Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories which are activated or hot from use can cause a fire.

Endoscopic Procedures

WARNING As visualisation may be impaired during endoscopy for a number of reasons, be particularly alert to these potential hazards:

- Ensure the tip of the instrument is visible before activation.
- The instrument tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of activated instruments outside of the field of vision may result in injury to the patient.
- Localised burns to the patient or physician may result from electrical currents carried through conductive objects. Electrical current may be generated in conductive objects by direct contact with the active instrument, or by the active or return instrument being in close proximity to the conductive object whilst activated.

- Carefully insert and withdraw active instruments from sheaths and working channels to avoid the possibility of damage to the devices and/or injury to the patient.
- Only activate during intermittent or preferably continuous flow irrigation to ensure good visualisation and cooling of the instrument tip between activations.
- The vaporisation process produces bubbles. Activation of the instrument tip within a bubble pocket may cause product damage.
- Only use normal saline irrigation solution. Do not activate when not in contact with tissue, or excessive heating of the irrigation medium may result.
- Tissue contact with the return instrument whilst the active instrument is surrounded by normal saline during activation may result in an electrosurgical effect occurring at the return instrument.

CAUTION Proper use of the system relies on tissue contact with the active tip of the instrument only. Do not bury the tip in tissue beyond the junction of the active instrument and the ceramic insulator as product damage may result during use.

WARNING Olympus TURis Mode
Incorrect assembly and connection of the Olympus Resectoscopic system and electrode may result in no RF surgical output.

IMPORTANT TURis compatibility is only available with SuperPulse software version V3.0 software and later.

2F. After Surgery

WARNING Electric Shock Hazard. Always unplug the generator before cleaning.

CAUTION Do not reuse or resterilize accessories labelled “disposable” or “single use only.”

2G EMC Classification

The SuperPulse System has been manufactured and tested to the following requirements:
Group 2 Class A as per IEC60601-1-2 (2001)

EMC PRECAUTIONS

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in this document.

EMC WARNINGS

- The generator should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary both the generator and other equipment should be observed to verify normal operation in the configuration in which it will be used.
- The EMC classification of the SuperPulse system (class A) is suitable for use on dedicated supply systems not connected to the public mains network, such as hospitals.

NOTE: Although class A limits have been derived for industrial and commercial establishments, administrations may allow, with whatever additional measures necessary, the installation and use of class A ISM equipment in a domestic establishment or establishment connected directly to domestic electricity power supplies.

- Portable and mobile RF communications equipment can affect medical electrical equipment.
- The use of accessories and cables other than those for which the system was designed can significantly degrade emissions and immunity performance.
- Keep the accessory cables away from cables from other electrical equipment. Electrical currents may be induced in the other equipment causing unintended effects.
- Do not use a monopolar generator/accessories simultaneously with the SuperPulse generator. Activation of a monopolar generator/accessories may cause interference with the SuperPulse generator resulting in user message changes on the display. Before proceeding with surgery, confirm proper power settings are displayed on the generator. Ensure the appropriate output setting is enabled for the desired surgical outcome.
- Provide as much separation as possible between the generator and other electronic equipment (such as monitors). When activating the generator, unintended electromagnetic coupling may cause interference with the other equipment.
- Should any unintentional effects appear upon other equipment when using the generator, repositioning the generator, the connecting leads or other equipment may alleviate the problem. It may also help to use different electrical supply sockets for any affected equipment

The SuperPulse Generator described in this manual, in conjunction with the available accessories, is designed to be used as a system to provide advanced electrosurgical effects during endoscopic urological surgery under normal saline irrigation.

3A. Responsibility of the Manufacturer

The manufacturer is responsible for safety, reliability and performance of the equipment only if:

- Installation procedures in this manual are followed.
- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorised by the manufacturer and the electrical installation of the relevant operating room complies with local codes and regulatory requirements.
- The equipment is used in accordance with this User Manual, the Instructions For Use which accompany all system components and any additional information contained on the component package labelling.

3B. SuperPulse Generator Power Requirements

Please refer to section 10-1 for full voltage detail.

Check the SuperPulse Generator Power Connection

The power connector meets all requirements for safe grounding. Its purpose should not be defeated by using extension cords or any form of adapter. When disconnecting from the mains socket or from the SuperPulse Generator, cords should always be grasped by the plug. Do not pull on the cord itself.

3C. Grounding of the SuperPulse Generator

To ensure user safety the SuperPulse Generator must be properly grounded through the inlet plug and power cord. Use only hospital grade power cords.

IMPORTANT Ensure that the electrical installation of the relevant room complies with local codes and regulatory requirements.

3D. Routine Maintenance of the SuperPulse Generator

It is recommended that the SuperPulse Generator be inspected by qualified service personnel in accordance with Section 13, Periodic Equipment Safety Checks.

4A. Gyrus ACMI SuperPulse Generator Indicators and Displays

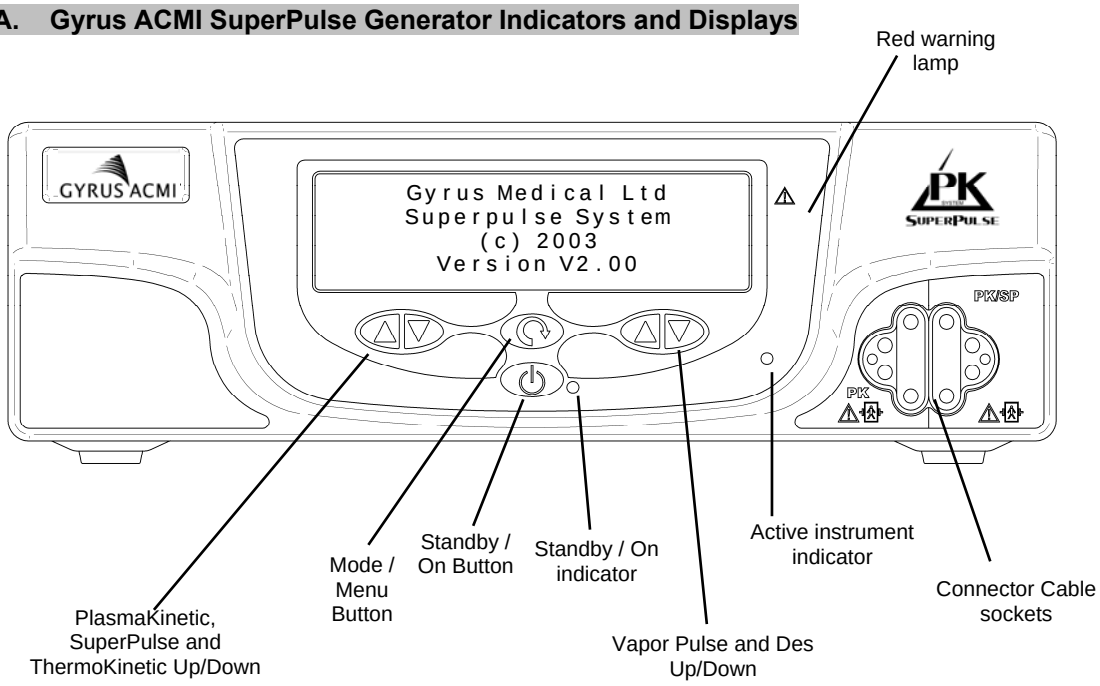


Fig 4. 1
Keypad : Standby/On, Up, Down Arrows and Mode / Menu Button

Standby / On

The Standby/On button switches the Generator back and forth between the Standby and Idle / Ready states. The green indicator will change from flashing to continuous when the equipment mode changes from Standby to Idle / Ready states by pressing the button. To place the generator into Standby press the standby button. When prompted press again to confirm entry to Standby is required

Following an error condition the generator may be reset by pressing the Standby / On button twice.

Up/Down Arrows

Depressing the up or down arrow when parameter change is permitted increases or decreases the parameter step-wise. Holding the button down will increase or decrease the value in preset steps

Mode / Menu

This button provides access into the waveform selection and setup menus.

Repeated short presses will give access to the frequently used functions, listed below: -

- Cut waveform selection (PK / SP)
- Coagulation waveform selection (VP / DES)
- Volume

A long press will give access to the setup menu, giving access to the following functions below with repeated short presses: -

- Display intensity
- Key click on/off
- Select language
- Enter PIN Code

NOTE If there is no user activity for a short period, the generator will exit the menu and return to Idle / Ready state.

When a PK connector cable is attached, the symbol below appears on the display.

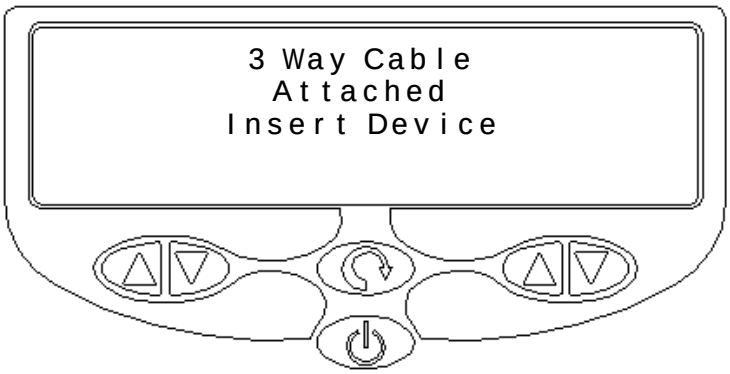


Fig 4.2 Screen for 3-Way PK cable installed on the selected socket.

Output Displays for SP/ PK Instruments

The display is split into two halves; the upper portion of the display is used to indicate the type of instrument active, that is the instrument that will provide an output when the Cut or Coag pedal is pressed. The lower half of the display indicates the output waveform type, or mode, and the power selected.

The left lower portion displays the mode selected and, underneath, the power level that will be active when the Cut pedal is depressed. This is dependent upon the type of instrument used, its default setting properties and any user power level adjustments.

When a Plasmakinetic™ (PK) instrument is used one of 'PK1', 'PK2' or 'PK3' is shown for the mode, the power setting can be from 10 to 200.

When a SuperPulse (SP) instrument is used one of 'SP1', 'SP2', 'SP3' is shown for the mode, the power setting can be from 10 to 320.

When the ThermoKinetic mode is selected 'TS1', 'TS2', 'T1' or 'T2' is shown.

The right portion displays desiccate (VP or DES), with the default power setting from 10 to 120 dependent on the type of Gyrus ACMI PK instrument attached. This is the power level that will be active when the Coag pedal is depressed.

The appropriate display will flash and an audible alarm will sound when an output is activated.

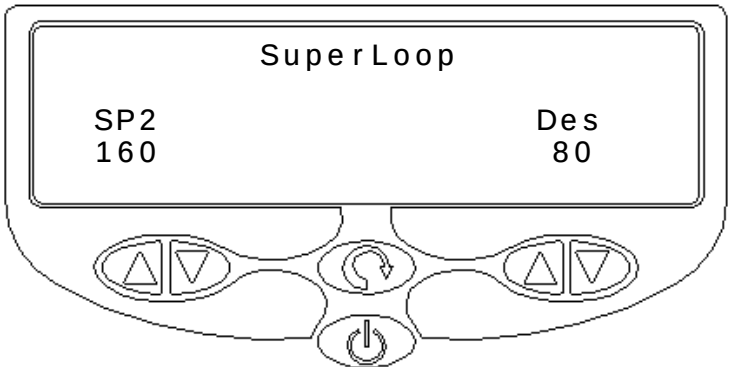


Fig 4.3 Screen for SuperLoop instrument selected

Output Displays for SP Instruments

The display will operate as per PK instruments with the PK waveforms replaced by their SP alternates.

IMPORTANT SuperPulse (SP) mode can only be used with Gyrus ACMI SuperPulse compatible instruments (SuperSect, SuperLoop and SuperV instruments).

4B. Output Mode Selection and Power Controls

When using a Gyrus ACMI instrument, the connected instrument is automatically sensed by the generator and the default power for that instrument will be selected.

Power Up/Down - These buttons adjust the power setting; the yellow arrow buttons for the PlasmaKinetic™ (PK), SuperPulse (SP) and ThermoKinetic (T and TS) outputs and the blue arrow buttons for the Vapor Pulse Coagulation (VP) and Desiccate (DES) output. Press the appropriate button once for a power increment or decrement. Holding down the button accelerates the incrementing or decrementing.

NOTE Power can only be adjusted once an instrument is properly connected to the generator. When using Gyrus ACMI instruments default output power and power range limiting is set appropriate to that instrument.

SuperPulse	SP3	Difficult high flow conditions and/or High impedance		
Cut	SP2	Moderate flow conditions		
	SP1	Low flow conditions	↑	Voltage increasing
PlasmaKinetic™	PK3	High impedance tissue (fatty, vascular tissue)		
Cut	PK2	Medium impedance tissue		
	PK1	Low impedance tissue (thin tissue)	↑	Voltage increasing
ThermoKinetic Cut				
(T)	T2	High impedance tissue (fatty, vascular tissue)		
	T1	Low impedance tissue (thin tissue)	↑	Voltage increasing
(TS)	TS1	Moderate tissue vascularity		
	TS2	Higher tissue vascularity	↑	Hemostasis decreasing

Coagulation	DES	General purpose, Non tissue-specific desiccation
	VP3	High impedance tissue (fatty, vascular tissue)
	VP2	Medium impedance tissue
	VP1	Low impedance tissue (thin tissue) ↑ Voltage increasing

NOTE Output mode selection can only be performed with an instrument and connector cable attached to the generator. The range of modes available will depend on the type of Gyrus ACMI PK instrument being used.

NOTE If the Mode / Menu button is quickly pressed and released the generator enters a menu based configuration state, pressing and holding the Mode / Menu button at any time exits this state.

NOTE The PK output is not available for some PK instruments. The lower left hand portion of the display remains blank in this case.

Mode Selection using Gyrus ACMI PK/SP Instruments - There are three PlasmaKinetic™ Modes shown as PK1, PK2 and PK3, which produce a tissue effect increasing from PK1 to PK3 (PK3 delivers power more effectively to higher impedance tissue than PK1). Two of the ThermoKinetic outputs available, shown as T1 and T2, continuously switch between a PlasmaKinetic™ and Desiccate output during activation. These ThermoKinetic outputs will provide a greater degree of hemostasis during tissue cutting compared to a PK setting.

Three VP mode levels and the desiccate (DES) are available.

VP1 is optimal for low impedance tissue, VP2 for intermediate impedance tissue and VP3 for higher impedance tissue or larger diameter instruments. The frequency of pulses in VP mode will also vary depending on the type of instrument attached: generally, the larger the tissue contact area, the slower the pulses. DES provides a conventional continuous bipolar output.

For instruments that support the SuperPulse waveform the PK modes are replaced by SP modes SP1, SP2, and SP3, producing an increasing tissue effect from SP1 to SP3. The SuperPulse modes provide high-energy pulses promoting rapid generation of the plasma corona around the active electrode. Once the plasma corona is established the output reverts to a continuous wave. The SP equivalents of the T1 and T2 ThermoKinetic outputs, TS1 and TS2 rely on selective modulation of the SP2 SuperPulse waveform, to provide a higher crest factor and therefore increased hemostasis.

The waveforms associated with the blue and yellow pedals can be individually assigned. To change the waveform press the Mode / Menu button until the option to change the waveform required is seen on the display (yellow pedal waveforms appear on the LHS and blue pedal waveforms on the RHS).

4C. TURis Mode for Olympus TURis Electrodes

The Gyrus ACMI SuperPulse System supports compatibility with the Olympus TURis Resectoscopic System.

When the supplied TURis cable is connected, the generator will automatically provide the default settings.
Modify the settings for the connected instrument to achieve the desired tissue effect.

TP Mode – Provides vaporisation/ cutting yellow pedal outputs for use with the Olympus TURis Electrodes (TP3 setting is more aggressive than TP1)

Refer to the instructions for use supplied with the compatible TURis Electrode range and the Olympus Resectoscope.

DES provides a Blue pedal coagulation output.

The outputs can be adjusted in the same manner as described in section 4B to suit physician preferences.

Using the UP/DOWN buttons as indicated on the screen, will cycle through the available waveforms for the respective pedal (see Fig. 4.4 below).

When the desired mode is displayed a further press on the Mode / Menu button will complete the selection

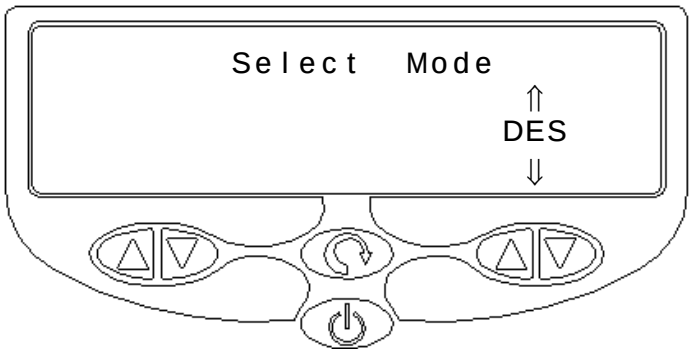


Fig 4.4 Screen for coag waveform selection

Socket Selection

The generator permits two instruments to be fitted simultaneously, via the two 5-way connectors.

Only one socket can deliver RF at any one time. When the generator is switched on from the Standby state, it initially operates an automatic socket selection mechanism, and assists primary connection by activating whichever socket first has an instrument attached. The instrument connected to the active socket is indicated on the display. Thereafter socket selection can only be altered manually, by pressing the black mode footswitch, ensuring that the surgeon always has control over which instrument is activated.

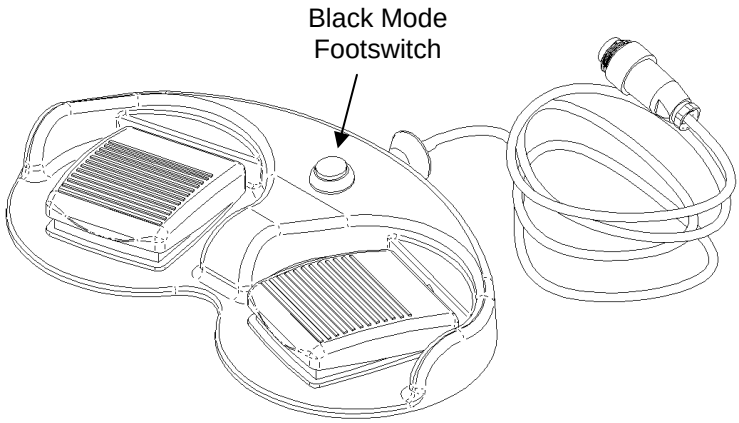


Fig 4.5 Footswitch

Footswitch - Blue Pedal
The blue footswitch pedal is used to administer desiccate and VP output waveforms. The output will be present while the footswitch is held down.

Footswitch – Yellow Pedal
The yellow footswitch pedal is used to administer ThermoKinetic and PK/SP (cut) waveforms. The output will be present while the footswitch is held down.

Footswitch – Black Mode Footswitch
The black mode footswitch enables a rapid change between instruments.

Generator Switch On/Off

The mains power On/Off rocker switch is located on the top left of the rear panel (viewed from front). The Generator is switched on by pressing the side marked I. The generator will display the Serial number of the generator, then the internal tests are performed then the green LED below the Mode / Menu button will come on continuously, and then flash after a short time. The generator is then in Idle state.

The generator display will dim after a period of 30 minutes of not being used and will automatically enter Standby state if it is not used for a period of four hours.

It is advisable to switch off the Generator whenever it is not in use for any extended period, by using the rear panel switch. The side marked "0" should be pressed to do this.

To enable use of the generator the Standby / On button must be pressed and the generator will then enter the idle state if no instrument is fitted or the Ready state if an instrument is fitted.

If an instrument is present at switch on then the user has to accept the default powers, by pressing the Mode / Menu button when prompted.

4D. SuperPulse Generator Indicators, Set-up and Malfunction Displays

Volume Adjustment - The activation tone volume can be adjusted between minimum and maximum using the up control of the desiccate (blue) power control. Depress and release the Mode / Menu button until the symbol **"SELECT VOLUME"** appears (Fig. 4.6). Press and release the Mode / Menu button once more to accept the setting.

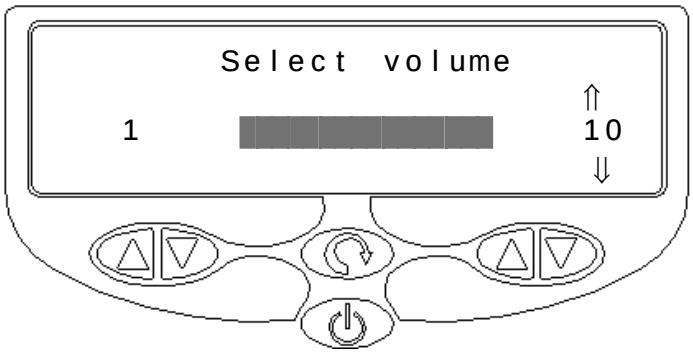


Fig 4.6 Screen for Alarm volume selection

System Failure Displays

Non-critical (Soft) Faults

Shorting - For Gyrus ACMI Urology instruments, if a Generator "Output Shorted" message occurs the power will be removed for 0.5 seconds and the activation tone will also be terminated for this time. If the pedal is kept depressed, RF activation will resume. If three short circuits occur in 2 seconds then RF activation is stopped until the pedal is released and pressed again. Power levels will remain the same as those previously in use.

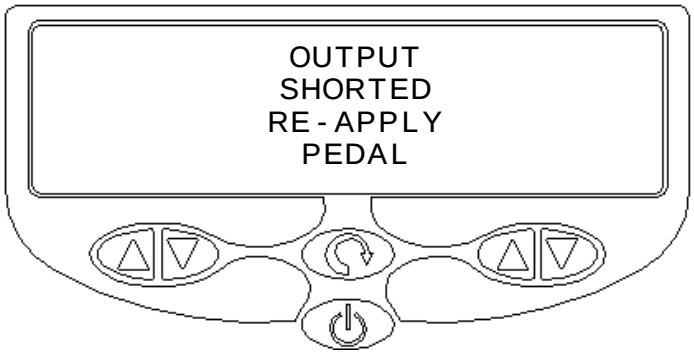


Fig 4.7 Screen for the selected SP electrode shorted

Storage at low temperatures – The generator will detect where the enclosure temperature is below the specified minimum allowable for use, and will display a 'WARMING UP" message until an acceptable temperature is reached internally, whereupon normal operation will resume. This condition is possible where the generator has been brought directly into the operating room from a cold storage environment.

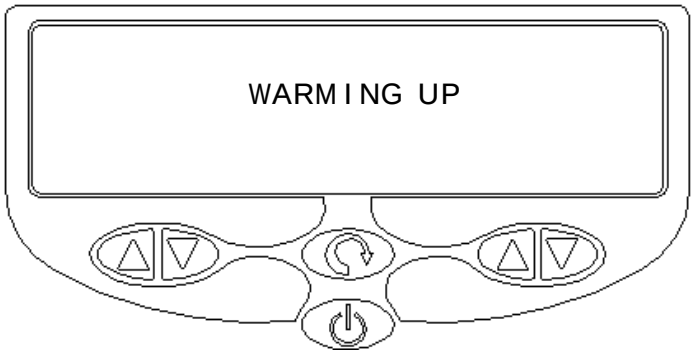


Fig 4.8 Screen for an excessively cold condition

Foot pedals stuck on – The generator will detect where one or more the foot pedals appears to be stuck on, and will wait until the condition disappears before resuming normal behaviour. This condition can be inadvertently caused by inverting the footswitch or standing on a pedal as the generator is switched on.

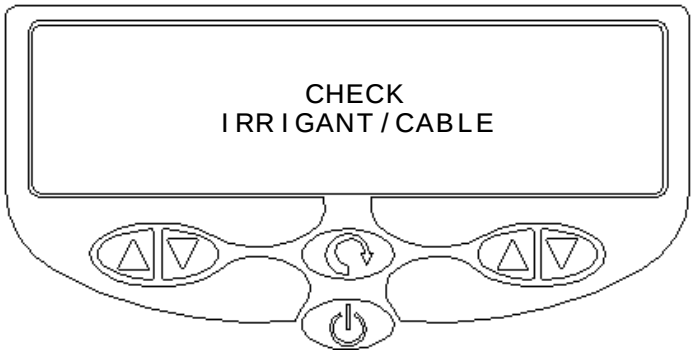


Fig 4.9 Saline Detection Mode in TURis Mode Only

If the SuperPulse Generator is activated when the electrode is not in saline or with only one Resectoscopic cable connection present the above message will be displayed. No RF output will occur.

Non-critical (Recoverable) Faults

Fault - If a fault is detected during set-up or during use a fault code message is displayed as indicated by the "Fault Code X00 REF XX" symbol on the front panel display (Fig 4.10 Screen for recoverable fault display). Refer to Section 9, Operating Room Troubleshooting.

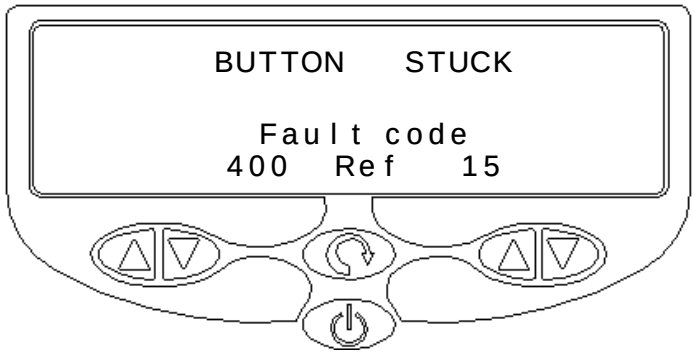


Fig 4.10 Screen for recoverable fault display

Critical (Non-recoverable) Errors

Red Warning Symbol - Except during the self-test routine and a non-critical failure, illumination of the red warning symbol on the front panel when accompanied by the **"**ERROR XXX REF XX**"** symbol (Fig 4.11 Screen for critical error display) on the front panel display indicates a critical failure. In the case of a critical failure, **DO NOT ATTEMPT TO USE THE UNIT**. Please refer to Section 11 for information.

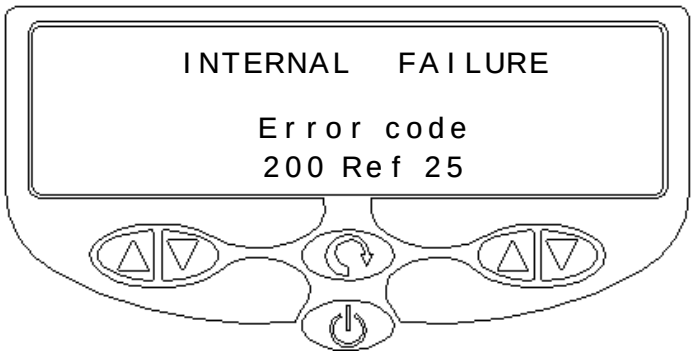


Fig 4.11 Screen for critical error display

SuperPulse Generator Connectors and Sockets

The PK Three Way connector cable is connected to the generator through either of the two PK connector cable socket on the front panel of the generator (figure 4.1).

The SuperPulse function is only available through the right hand socket and the SuperPulse instruments must therefore be connected to this socket. Olympus TURis mode is only available from this socket.

The mains power cord; footswitch cable and protective earth cable are connected to the generator through fittings on the rear panel.

4E. CHANGING THE DISPLAY LANGUAGE

From the SuperPulse generator idle state (with the VFD screen showing the “Connect PK Cable” or “X Way Cable Attached Insert Device” message), press and hold for 3 seconds the Mode / Menu button on the SuperPulse front panel.

The SuperPulse generator VFD screen will show the “Display Intensity” message, press and release the Mode / Menu button twice so the following screen is displayed.

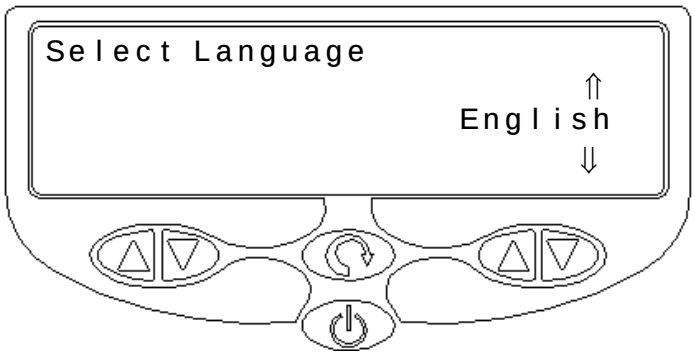


Fig 4.12

Use the right hand arrow buttons to change the language as required. Press and hold the Mode / Menu button down to return to the previous state.

Once the language has been changed from the factory default of English, the SuperPulse will continue to use the selected language for all instructions, performance information and error messages on the generator VFD display.

4F. ENABLING ADDITIONAL INSTRUMENTS VIA A PIN CODE

As additional instruments are released for use with the SuperPulse generator these can be added to the SuperPulse generator software and enabled for use. This is done by entering a PIN code into the SuperPulse generator using the front panel buttons. The PIN must be entered twice in succession to enable these instruments.

Once the PIN has been entered, the SuperPulse generator can then use these additional instruments.

Your local sales representative can provide you with this information as it becomes necessary or alternatively contact Customer Services as detailed at the front of this manual.

The enabling of these instruments is a one off action that must be performed in order to use these additional instruments. The SuperPulse generator will remember that PIN and continue to allow the use of these instruments even after it has been switched off.

This facility can be setup in one of two ways:-

Note: If the PIN number entry screen cannot be accessed, contact your local sales representative, or alternatively contact Customer Services as detailed at the front of this manual.

a) Without instrument available at the time of PIN entry

This option can be done at any time prior to surgery.

From the SuperPulse generator Idle state (showing the “Connect PK Cable” or “Insert Device” message) press and hold for 3 seconds the Mode / Menu button on the SuperPulse generator front panel.

The SuperPulse generator VFD screen will show the “Display Intensity” screen, press and release the Mode / Menu button three times so the SuperPulse generator displays the following screen.

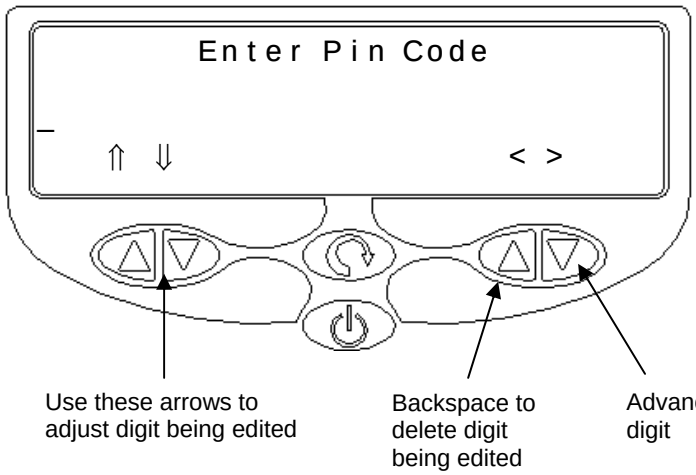

Enter Pin Code
⇑ ⇓
< >
Use these arrows to adjust digit being edited
Backspace to delete digit being edited
Advance to next digit

Fig 4.13

Once the PIN code has been entered and is displayed correctly then press the Mode / Menu button, the display will change to that shown in Fig 4.14 below.

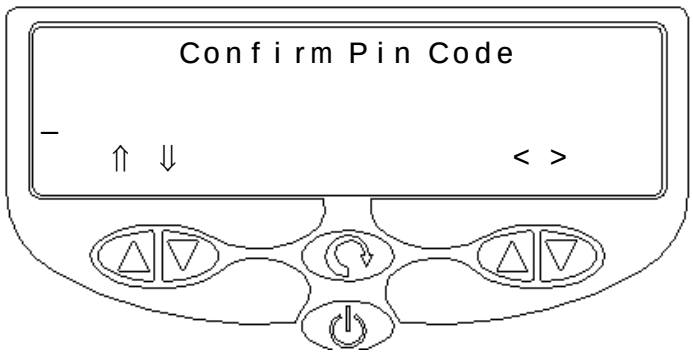


Fig 4.14

Re-enter the PIN code using the same procedure, once this is correctly displayed press the Mode / Menu button, the SuperPulse generator will bleep to acknowledge the PIN entry.

If the code is entered incorrectly then the following display will be shown

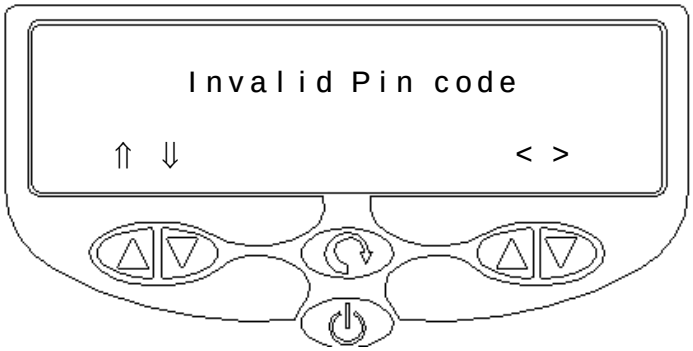


Fig 4.15

The PIN entry sequence must then be repeated, press any arrow button to restart the PIN entry sequence.

Note: If the PIN Entry screen is left displayed for two minutes at any time without any buttons being pressed the SuperPulse will return to its default screen “Connect PK Cable” or “Insert Device” and the PIN entry process will have failed and will need to be repeated.

b) With Instrument available at time of PIN entry.

This allows the instrument to be enabled at the start of the surgery if it has not been done previously. Insert the instrument, if the following display is shown on the VFD,

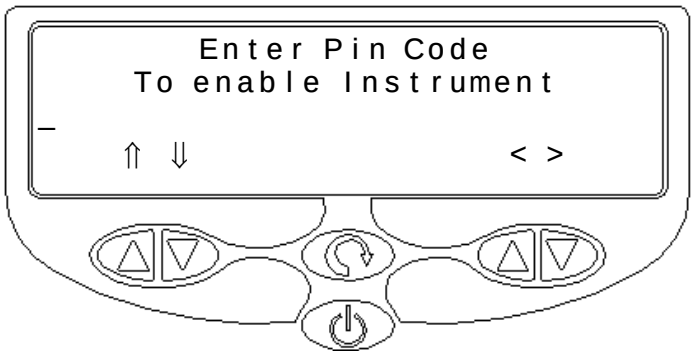
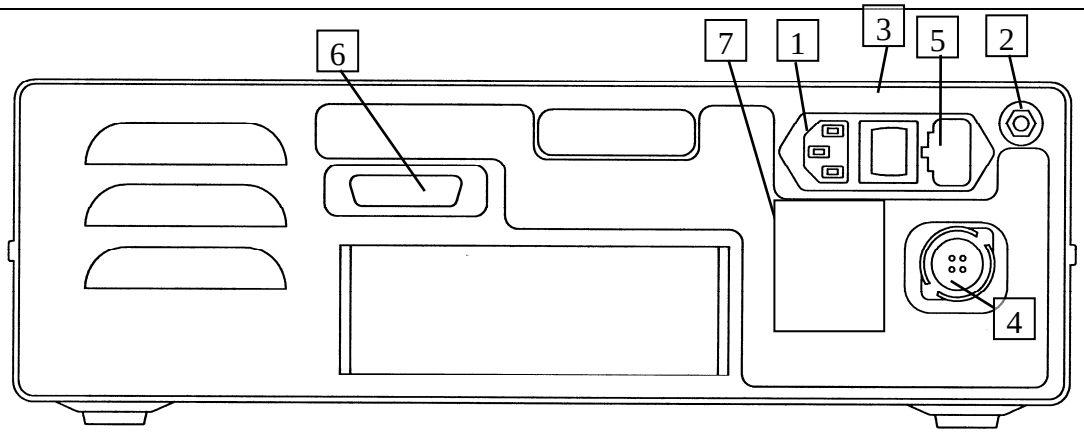


Fig 4.16

then the PIN code must be entered as detailed previously in section 4F, however no timeout will occur when the instrument is connected.



1. **AC Power Connector**
   Connector for the AC line power cable.

2. **Equipotential Connector**
   The connection for the Potential Equalization Conductor terminates at this point.

3. **Power Switch**
   Switch to turn the Generator on/off.

4. **Footswitch Connector**
   The Footswitch is used to initiate the RF On & Mode.

5. **Fuse Compartment**
   Location of line fuses.

⚠ **WARNING:** Replace only with T-series 10A, 250V fuse certified to IEC 127 (5 x 20 mm fuse).

6. **RS232 Connector**
   Used by qualified Gyrus ACMI technical personnel only. Do not connect any device to this port.

7. **Fuse Label**
   Provides information on correct fuse to use for fuse replacement.

Fig 4.17

This section describes how to set up the Gyrus ACMI SuperPulse Endourology System before surgery. Prior to using the system, you should ensure that the following associated equipment has been prepared for use:

- A sterilised PlasmaKinetic™ Resectoscope or a urological endoscope with a 5 Fr. or larger working channel.
- A sufficient quantity of Normal Saline irrigant solution to complete the procedure.
- A minimum of 2 appropriate PlasmaKinetic™ or Olympus TURis devices for the procedure to be performed.
- A sterilized reusable PlasmaKinetic™ Connector Cable if required.

5A. Power up the SuperPulse Generator

Install the SuperPulse Generator

- Place the SuperPulse Generator on a table, cart, racking system or other stable platform that can be positioned as close as possible to the operative site during use.
- Ensure that the SuperPulse Generator is standing on a flat, firm surface and that it is not at risk of being accidentally dislodged during the course of operating theatre activity.
- Provide at least four inches of space from the rear of the SuperPulse Generator. Never cover the SuperPulse Generator or stack other equipment on top of it. It is normal for the SuperPulse Generator to become warm during use so ensure adequate ventilation.

Connect the SuperPulse Generator

Plug the supplied AC power cord into the receptacle on the rear of the SuperPulse Generator and then connect the other end of the cord directly to an AC power point. Avoid the use of extension cords or multiple plug adapters. Wherever possible, avoid trailing leads and neatly store excess power cord.

Connect the Footswitch

Connect the dual pedal footswitch to the receptacle at the rear of the SuperPulse Generator by orientating the lug on the plug with the groove in the receptacle and pushing the plug into place. Secure the plug by screwing down the locking ring in a clockwise direction.

Switch the SuperPulse Generator On

Apply mains power to the generator by operating the On/Off rocker switch located on the rear panel. Verify the completion of the system initialisation sequence of tests by observing the increasing numeral display.

The ‘Attach PK Cable’ message confirms that the system is in idle state and is now ready for use with any connected instrument.

5B. Select the Appropriate PK/SP Instrument(s) for the Procedure

Instrument Default Settings

For your convenience and to improve safety during use, all Gyrus ACMI instruments have an internal identification code, which is interrogated by the SuperPulse Generator when the instrument is attached. Default settings and power set adjustment limits are then set appropriately for that particular instrument.

Types of Gyrus ACMI PK Instrument

There are two fundamental categories of PlasmaKinetic™ instruments; those for use with Resectoscopes and those for use with urology endoscopes e.g. Cystoscopes.
For information on the assembly of Resectoscope/Endoscope/Instruments also refer to the supplied Instruction for Use.

PlasmaKinetic™ Resectoscope and PlasmaKinetic™ SuperSect/Loop Resectoscope Instruments

The PlasmaKinetic™ Resectoscope Instruments require that both poles of the electrosurgical circuit be connected to the instrument. As conventional monopolar resectoscopes are only equipped to accept one electrical connection, the PlasmaKinetic™ Resectoscope instrument must be used with a PlasmaKinetic™ Resectoscope. The PlasmaKinetic™ Resectoscope is available with either active or passive working elements.

PK SuperSect/Loop Resectoscope instruments (figure 5.1 SuperLoop instrument and figure 5.2 instrument tip) are designed to provide rapid tissue resection, vaporization or desiccation. Unlike monopolar vaporisation techniques, the Gyrus ACMI system will vaporise tissue effectively irrespective of the number of times the device has been passed over the tissue surface. This is due to the fact that the current flows only through the tissue being vaporised.

Fig 5.1

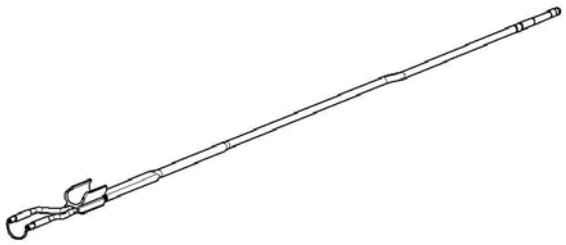
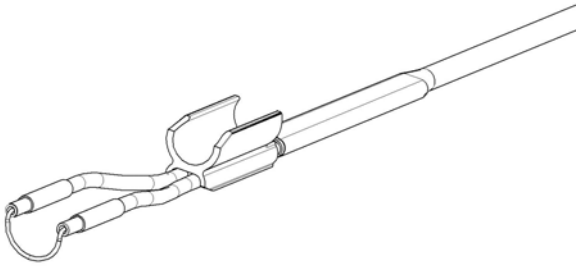


Fig 5.2



Types of Olympus PK TURis Instruments

The Olympus PK TURis range of instruments is compatible with the SuperPulse Generator and should be connected to the right hand SuperPulse socket.
Assemble the Olympus Resectoscope and Instruments before inserting the connector into the SuperPulse Generator socket.

IMPORTANT **Ensure saline is used as the irrigant.**

PlasmaKinetic™ Cystoscope Instruments

The PlasmaKinetic™ Cystoscope Instruments are designed to fit through endoscopes with a working channel of 5Fr. or larger (with the appropriate septum cap).

The intended use of the PlasmaKinetic™ Cystoscope instruments is to perform vaporisation and desiccation of soft tissue pathologies using endoscopes such as cystoscopes or urethroscopes with 5 Fr. or larger working channels. The tip design of these instruments falls into two categories:

- Coiled active tips - primarily intended to provide vaporisation and instantaneous coagulation of tissues (figure 5.3a).
- Wire active tips - primarily intended to provide cutting of soft tissues.

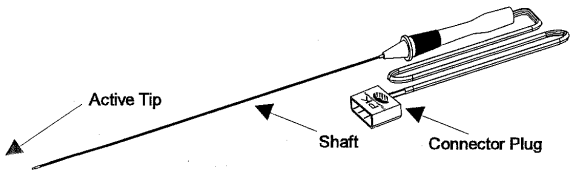


Fig 5.3

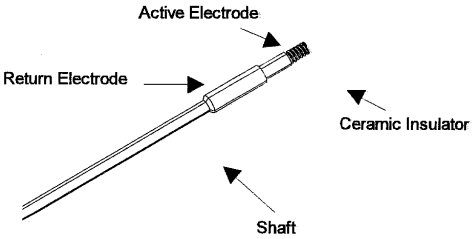


Fig 5.3a

NOTE Specific information regarding the instrument classification codes are provided on the instrument package labelling.

5C. Steam Sterilise the PK Connector Cable, PlasmaKinetic™ Resectoscope or appropriate urological endoscope

Please refer to the PK Connector Cable Instructions for Use and PlasmaKinetic™ Resectoscope User Manual for their respective recommended sterilisation procedures. Refer to manufacturer's instructions for urological endoscope sterilisation procedure.

5D. Connect the PK Connector Cable or TURis Connector Cable

Introduce the sterile connector cable to the sterile instrument table or trolley according to the sterile handling practices at your facility.
The cable and connectors should be inspected for any processing damage.

IMPORTANT If any of the connector pins are bent or if the cable shows any signs of crush damage, cracking or distortion, it must be discarded.

The SuperPulse Generator end of the connector cable should then be passed to a non-sterile operative for connection to the SuperPulse Generator. Ensure that sufficient length of cable is retained for connection to the instrument, that sufficient slack is provided so that operation is not impeded, and that sufficient slack is also allowed for tethering to the surgical drapes.

Urological endoscope

The urological endoscope should be prepared for use according to the manufacturer's instructions.

NOTE The PlasmaKinetic™ Cystoscope instrument would normally be attached to the connector cable prior to its introduction into the working channel. See section 5F for attachment instructions.

Introducing the PlasmaKinetic™ Cystoscope Instrument through the working channel

With the endoscope having been introduced through the urethra, pass the instrument through the working channel ensuring that the working channel tap is in the fully open position prior to introduction.
Once the instrument is inserted, tether excess cable flex to the sterile drapes to prevent dragging during manipulation.

WARNING Avoid the use of excessive force when inserting instruments through a working channel. Angled working channels often include changes in internal diameter which may obstruct free passage. If the free passage of the instrument is obstructed, remove and try again rather than trying to force the instrument tip past the obstruction. Using force to overcome obstruction will result in damage to the instrument tip and risk malfunction or breakage during use.

5E Attaching PlasmaKinetic™ Instrument via the PK Connector Cable

Connect the PK instrument to the PK Connector Cable by aligning the two connector halves using the moulded orientation marks and then pushing together. Once connection is made, the 'Insert Device' symbol (Fig 4.2) flashing on the SuperPulse Generator display will change to the default settings appropriate to the instrument classification code.

For safety and convenience, PK instruments automatically pre-set the SuperPulse Generator to default output settings and restrict output levels to preserve instrument integrity.

5F Attaching TURis Instruments to the Generator

Assemble the Olympus Resectoscope according to the instructions supplied. Connect both connectors on the supplied cable to the Resectoscope. Insert the selected Olympus TURis Electrode into the Resectoscope.

Then attach the cable to the right hand socket of the Gyrus ACMI SuperPulse Generator (marked PK/SP). The generator screen will change to show default settings. Modify the generator settings as indicated and as necessary to achieve the desired tissue affect.

Connect TURis to the right hand SuperPulse socket only as shown in Fig 5.4

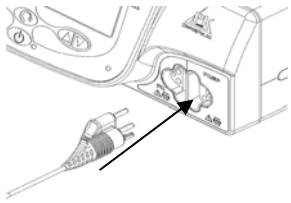


Fig 5.4

This section describes how to use the Gyrus ACMI SuperPulse Endourology System during surgery.

6A. Accessories

IMPORTANT Use only approved PlasmaKinetic™ or Olympus TURis Instruments, Connector Cables and Resectoscopes. Instruments, connector cables and resectoscopes other than those approved accessories with the Gyrus ACMI SuperPulse Endourology System must not be used. The Gyrus ACMI SuperPulse Generator and Endourology surgical accessory has been designed as a system, with accessory features specifically designed to maximise safety and effectiveness. Unless the SuperPulse Generator is able to interrogate the correct identification code contained within the instrument to establish the optimum default settings, all output functions will be disabled.

6B. Recommendations During Surgery

- Refer to the cautions and warnings at the front of this manual.
- Unless circumstances dictate otherwise, use the instrument default settings to enhance patient and user safety.
- Remove any gross tissue build-up from instruments to maximise surgical effect.
- Avoid any unnecessary and prolonged activation to prevent overheating.
- When debulking or vaporising tissue use a progressive surface shaving technique, rather than burying the instrument in tissue, in order to reduce debris and control the effect to the area of treatment.
- The active and return elements of the instrument tip must be fully immersed in saline irrigant before activation. Failure to do this will cause malfunction of the equipment.
- Avoid activation of the instrument within a working channel or operating sheath.
- Bubbles are produced during tissue vaporisation which may interrupt surgery by temporarily interfering with vision. Sufficient flow of irrigant is recommended to ensure that these bubbles are flushed away from the field of view and from the area surrounding the active tip of the PlasmaKinetic™ Instrument. If not using continuous flow irrigation it is important that the bladder is drained as soon as the irrigant flow rate is seen to diminish.

CAUTION Do not attempt to crush or remove prostatic calculi by trapping between the instrument tip and the resectoscope beak. This practice may damage the tip of the instrument or the resectoscope working element.

Use of Default Power Settings

The power settings used for the intended procedures vary considerably both with the surgeon's technique and the configuration of the active instrument. The PlasmaKinetic™ instruments are unique to the type of procedure being undertaken and some experience may be required before optimal power settings to suit the particular surgical technique are determined.

The Gyrus ACMI SuperPulse Endourology System has an output power capability more equivalent to a monopolar electrosurgical unit than a conventional bipolar electrosurgical unit. Until the surgeon becomes familiar with the characteristics of the system, caution should be used in increasing power output levels above the instrument default settings.

It should be noted that the SuperPulse Generator incorporates a PK mode output power boost feature when connected to a PK Plasma-V Resectoscope Instrument. This boost functions by automatically

increasing the selected power output setting of the SuperPulse Generator by 25% during the first 400 milliseconds of cut activation, up to a maximum output of 200W.

Use of Default Mode Settings

Similar to power settings, the mode selection for procedures vary considerably both with the surgeon's technique and the configuration of the active instrument. The PlasmaKinetic™ instruments are unique to the type of procedure being undertaken and may require some experience before the effects of the different mode settings become apparent.

PlasmaKinetic™ (PK)/SuperPulse (SP) Modes:

The three PK/SP mode levels adjust the tissue effect of the output: PK3/SP3 > PK2/SP2 > PK1/SP1, the more aggressive tissue vaporisation produced by a PK3/SP3 selection. More aggressive tissue vaporisation will produce more vapour bubble formation.

CAUTION The formation of vapour bubbles may obscure visualisation during activation particularly when operating in a very confined space or during reduced irrigation flow. Use caution when adjusting the PK/SP modes in these circumstances.

ThermoKinetic (T and TS) Modes:

Two of the ThermoKinetic outputs are available for use with all PK instrument configurations. These are indicated as 'T1' and 'T2' on the power setting display. In both options, the output is automatically switched between PlasmaKinetic™ and Desiccate modes to produce more haemostasis than the pure PK outputs, while still providing tissue vaporisation. ThermoKinetic 1 (T1) switches between PK2 and DES five hundred times per second while ThermoKinetic 2 (T2) alternates between PK3 and DES approximately thirty times per second. The actual tissue effects observed with T1 and T2 are to a large degree dependant on the nature of the tissue being treated. As a generalisation however, T1 produces a superficial blanching of tissue with little to no vaporisation while T2 produces a level of vaporisation equivalent to PK1 with an enhanced haemostatic effect. Instruments that use the SP mode also have access to two additional ThermoKinetic outputs, indicated as 'TS1' and 'TS2' on the power setting display. The method for providing increased hemostasis with these outputs relies on selectively modulating the SP2 output at half-millisecond steps when contact with tissue is detected. The TS2 has a higher crest factor than the TS1 output and so provides more hemostasis. A vibration may be mildly discernable, indicative of this process.

Desiccate (DES) Mode:

The DES output is available with all PK instrument configurations. The haemostatic effect will be dependent on the active instrument contact area and power setting. The output is specifically controlled to prevent vaporisation from occurring and to provide a soft coagulation effect. The depth of effect for a given PK instrument configuration and power setting will be dependent on the application time.
Activation: Output Selection
In common with conventional electrosurgical generators, output activation is achieved using the blue and yellow pedals of the footswitch.
BLUE PEDAL: Desiccate only. Activation accompanied by flashing of the desiccate power display and an audible tone.

YELLOW PEDAL: PlasmaKinetic™ 1, 2, 3, SuperPulse 1, 2, 3 and ThermoKinetic T1, T2, TS1 and TS2 depending on output mode selection. Activation is accompanied by flashing of the SP/PK or T power display and a higher pitched audible tone than the desiccate activate tone.

IMPORTANT Familiarise yourself with the two audible output tones to verify output selection as it is often difficult to visualise the footswitch pedals during surgery.

Changing Output Mode and Power Setting during Surgery

In Ready mode, power adjustment can be made at any time other than while activated or while the SuperPulse Generator displays a malfunction. The permissible range of power adjustment will be limited by the instrument classification code.

Adjustment of output modes: PK1/SP1, PK2/SP2, PK3/SP3, T1, T2, TS1 and TS2 can be changed at any time other than while activated or while the SuperPulse Generator displays a malfunction.

Output Warning indication during Surgery

For Gyrus ACMI Urology instruments, if a Generator "Output Shorted" message occurs the power will be removed for 0.5 seconds and the activation tone will also be terminated for this time. If the pedal is kept depressed, RF activation will resume. If three short circuits occur in 2 seconds then RF activation is stopped until the pedal is released and pressed again. Power levels will remain the same as those previously in use.

Changing Instruments During Surgery

An instrument can be detached from the connector cable and removed from the endoscope simply by reversing the instructions for installing the PlasmaKinetic™ Instrument.
Once the instrument is disconnected, the SuperPulse Generator will automatically enter the idle state with the display showing the **'X Way Cable Attached Insert Device'** symbol where X is "3" or "5" depending upon cable type connected. (Fig 4.2 Screen for 3-Way PK cable installed on the selected socket).

Inserting a new PlasmaKinetic™ instrument configuration will reset the SuperPulse Generator to the default settings for that specific instrument. Unless the instrument has the same identification code, any adjustments to the SuperPulse Generator settings made when using the previous instrument will be overridden.
If using Olympus TURis instruments select the required settings for the connected instrument to achieve the desired tissue effect.

Changing Accessories Between Procedures

Section 8 describes the disconnection of the PK connector cable and instrument.

Once the PK connector cable is disconnected, the SuperPulse Generator will automatically enter the idle state with the display showing the **'X Way Cable Attached Insert Device'** symbol where X is "3" or "5" depending upon cable type connected. (Fig 4.2 Screen for 3-Way PK cable installed on the selected socket).

The SuperPulse Generator can be left in the idle state between procedures.

CAUTION If the SuperPulse Generator is maintained in the idle state between procedures and the same instrument configuration is employed for the next procedure, then any adjustments made to the output settings during the previous procedure will be remembered and will supersede the default settings.

Switching the power off will clear all output adjustments and, on subsequent use, the output will assume the default settings for the selected instrument.

- Whether using a PK resectoscope or cystoscope instrument, tissue removal rate using the PK/SP output modes is optimised by keeping the instrument in continuous motion during firm application against the tissue surface. It is normal for some superficial browning and carbonisation to occur during resection. At the conclusion of the procedure, this can be simply removed by softly brushing the instrument over the surface. To desiccate or coagulate a bleeding site, the instrument tip should be applied to the site using firm pressure. Once positioned, activate the desiccate output until visible blanching is observed around the application site

- Transurethral prostatectomy can be performed using the familiar techniques of monopolar electrosurgery with the instrument stroke removing a similar volume of tissue by vaporisation as that achieved using a monopolar loop. To optimise the advantages of the Gyrus ACMI PlasmaKinetic™ System and avoid creation of loose tissue pieces, the resection surface should be kept as even as possible. Undercutting of resection margins, varying the application pressure during activation and burying of the instrument beyond half its circumference can result in an irregular surface and the production of loose tissue pieces. Irregularities or tissue tags produced during resection are best removed using a firm side-to-side, surface application rather then the conventional proximal to distal cutting action of a monopolar loop.

- If more vascular or glandular prostatic tissue is encountered, one of the four ThermoKinetic modes can be selected to increase collateral thermal effect at the resection margin.

- The maintenance of good irrigation flow during resection is important to remove the bubbles and particulates created during vaporisation. Very high flow can suppress performance and some adjustment may be necessary to optimise the balance.

- Placing the PK instrument against the tissue before activation is both good surgical practice and provides more repeatable performance.

- The PlasmaKinetic™ Cystoscope Instruments may be used with other endoscopes such as urethroscopes or laser resectoscopes provided that the 5 Fr. shaft and tip of the instrument will pass through the working channel.

- When using the PlasmaKinetic™ Cystoscope Instruments, some modification of technique is required when resecting villous bladder tumours if the tissue pieces produced by conventional resection techniques are to be avoided. The use of firm pressure will amputate the villi so it is advisable to shrink these using the desiccate output combined with gentle application of the instrument prior to vaporisation. Clearly, this technique should only be used when there is an established histological diagnosis.

- If an instrument is being used in the urethra, care should be taken to avoid unnecessary activation and the risk of thermal damage beyond the application site. This particularly applies when dividing strictures which prevent good irrigation flow during activation.

After surgery, the following steps should be performed:

8A. Following Surgery involving PlasmaKinetic™ Resectoscope Instruments

a) Detach the instrument from the PK connector cable by grasping the two halves of the connector by the moulded finger grips and pulling apart.

CAUTION Always detach by grasping the connector grips and not the cable(s). Failure to do so may result in product damage.

b) Remove the instrument from the working element.

c) Dispose of the SINGLE USE instrument(s) and single use connecting cables according to your facility's policy on the destruction of surgical waste.
Gyrus ACMI provides both reusable and disposable connecting cables check which is used by your facility

d) Disconnect the PK connector cable from the SuperPulse Generator by grasping the plug and pulling gently from its socket on the front of the SuperPulse Generator.

e) The resectoscope components, including the telescope are suitable for manual or machine washing. If automated instrument washing systems are to be used and the components are heavily soiled, it is recommended that they are pre-washed manually.

Manual washing should be carried out using a soft sponge or brush and a mild cleaning solution or detergent capable of removing organic deposits.

f) The lumen of both inner and outer sheaths should be cleaned thoroughly using an appropriately sized brush. Particular attention should be paid to the inlet and outlet nozzles and also the stop taps.

g) All taps should be open or disassembled during both cleaning and sterilisation to allow the free flow of cleansing/sterilising agents.

h) After cleaning, the components must be rinsed with water to remove residual cleaning agent and then dried thoroughly, using compressed air if necessary. Taps should be disassembled and re-greased prior to sterilisation.

i) Sterilise the Resectoscope according to the recommended procedure described in the Resectoscope User Manual.

8B. Following Surgery involving PlasmaKinetic™ Cystoscope Instruments

a) Remove the instrument from the urological endoscope

b) Clean and sterilise the urological endoscope according to the manufacturer's instructions.

c) Disassemble the instrument and connector cable as described for the PlasmaKinetic™ Resectoscope Instruments above.

d) Dispose of the SINGLE USE instrument(s) according to your facility's policy on disposal of biologically contaminated waste.

8C. Following all Surgery involving the Gyrus ACMI SuperPulse Endourology System

If using the reusable cable (3900/3905) clean and sterilise the PK Connector Cable.
Prepare the PK connector cable for steam sterilisation according to the following cleaning procedure:

a) Remove all gross matter (blood, mucus, tissue etc.) by wiping the reusable Connector Cable with a cloth or gauze pad and a mild cleaning solution or detergent capable of removing organic deposits.

IMPORTANT To avoid damage to the cable and connectors do not immerse in reprocessing solutions or use abrasive cleaning agents.

b) Rinse thoroughly in running water.

c) Remove residual cleaning agents with a water damp cloth.

d) Dry the device thoroughly before sterilising.

Sterilise the connector cable according to the sterilisation procedure described in the Connector Cable Instructions For Use.

IMPORTANT The connector cable supplied as part of the Gyrus ACMI SuperPulse Endourology System is intended for 20 re-use cycles only.

WARNING Do not attempt to re-use PlasmaKinetic™ Instruments. Heat or chemical sterilisation may render the instrument mechanically or electrically unsafe.

WARNING Exceeding the recommended number of uses may result in electrical or mechanical failure during use or difficulty when attaching or detaching the instrument to or from the reusable connector cable.

Clean the Footswitch

a) Disconnect the footswitch from the rear panel of the SuperPulse Generator by first unlocking the retaining ring by rotating in an anti-clockwise direction and then withdrawing the plug from its receptacle.

WARNING Do not pull on the footswitch cable prior to unscrewing the connector locking ring. Such action may cause malfunction or intermittent activation during use.

b) Remove all gross matter (blood, mucus, tissue) by wiping each component with a cloth or gauze pad and a mild cleaning solution or detergent capable of removing organic deposits.

IMPORTANT Do not immerse in reprocessing solutions. Do not use abrasive cleaning agents. Do not use ultrasonic cleaners. Product damage may otherwise result.

c) Remove residual cleansing agents with a water dampened cloth.

WARNING The Footswitch is not designed to be sterilised. Sterilisation could lead to product damage or malfunction during use.

Clean the SuperPulse Generator

Use a mild antibacterial detergent on a damp cloth to clean the SuperPulse Generator. Do not allow fluids to enter the SuperPulse Generator connectors. Do not use caustic, corrosive, or abrasive cleaning materials. The SuperPulse Generator can not be sterilised.

SECTION 9 OPERATING ROOM TROUBLESHOOTING

Problem	Suggestions/Solutions
No output power	• Check cable and instrument connections. • Request assistance from Gyrus ACMI Service Support.
Generator resets during activation	• Check grounding of generator. • Check insulation of connector cable. • Check integrity of instrument. • Ensure no contact was made with other equipment during activation.
Red warning symbol illuminates	• Refer to fault code in section 12 and request assistance as necessary.
Unable to activate the generator	• Check footswitch for damage • Ensure approved footswitch is attached.
Alarm tone too loud or too quiet	• Re-adjust volume by means of the Mode / Menu button. Generator will remember the last volume setting employed.
No display on the generator	• Check the inlet fuse, replace with the correct type if necessary; request assistance from qualified service engineer if fault persists.
Generator flashes **"Attach PK Cable"** after cable inserted	• Verify that the cable connector is fully inserted. • Check for damage to cable flex. • Remove connector and inspect pins for damage. • Ensure only approved accessories are being used.
Generator flashes **"Insert Device"** or **"Invalid Accessory"** after instrument attached	• Ensure the connector cable contacts are clean and dry and have not been damaged during reprocessing. • Check instrument and cable integrity. • Ensure only approved instruments and accessories are being used. • Move cables away from any possible source of interference e.g. other active electrosurgical systems. • Ensure Olympus TURis connector cable is inserted in right hand SuperPulse socket.
Generator overheats	• Allow generator to cool down before re-use. • Check that sufficient ventilation is provided around generator. • Ensure ambient temperature is within operating limits.
Generator displays **"Press mode to use"** when attempting to activate.	• The generator has detected external interference and requires user confirmation of the instrument type. Press either the Mode / Menu button on the generator or the black mode footswitch to confirm. Note: any confirmation will only be required once per instrument connection.
Generator flashes **"SP ELECTRODE IN LHS"** after instrument attached	• Ensure that any SP supported instrument is **only** connected to the Right Hand Side, SP/PK socket. • Check for damage to cable flex and instrument. • Move cables away from any possible source of interference e.g. other active electrosurgical systems.
Generator displays an error message during activation	• Check for activation of instrument within the working channel or sheath. • Contact may have been made with other equipment during activation such as cystoscope or other instrumentation. • Remove the instrument from the operative site and inspect both it and the cystoscope for damage. • Reset the Generator from the black mode footswitch. • Check the accessories by activating the instrument in irrigating fluid contained in a bowl or similar, remote from patient contact before proceeding with surgery. • If the fault recurs, first replace the instrument and recheck. • If the fault continues, contact technical service.
Generator does not respond to instrument when attached.	• To ensure your SuperPulse generator is compatible with the latest range of Gyrus ACMI instruments please ensure that the SuperPulse software is updated with the latest available revision - contact your local Gyrus ACMI sales representative / technical service to arrange.
Generator Displays "CHECK IRRIGANT/CABLE"	• Ensure only saline is used as the irrigant • Ensure both cable connections at the Olympus Resectoscope are secure.

Environmental Conditions

Transport and Storage	Ambient Temperature	0 to 50 °C
	Relative Humidity	10% to 90% non-condensing
	Atmospheric pressure	500 to 1060mBar
Operation	Ambient Temperature	10 to 40 °C
	Relative Humidity	10% to 90% non-condensing
	Atmospheric pressure	500 to 1060mBar

SuperPulse Generator Power Source

	Operating Range	Nominal 100-120 V, 220-240 Volts RMS 50/60 Hz, 1000VA
	Regulation Voltage	90-132/198-264 Volts RMS
	Inlet Fuses	Time lag 10A (T10A) 250V

SuperPulse Generator Weight 8 kg (18 pounds) (approx.)

SuperPulse Generator Overall Dimensions
410 x 410 x 135 mm (16.14” x 16.14” x 5.3”) (approx with rubber feet) (DxWxH)

SuperPulse Generator Earth Leakage Currents
< 300 µA

Alarm Volume — Adjustable between 40dB (minimum) and 65dB (maximum) at 1m. This is an activation signal only.

Classification — Class 1 (IEC 60601-1)

Electromagnetic Compatibility — Complies with IEC 60601-1-2

Defibrillator Proof — Type BF equipment with isolated (F) applied part. Each of the instrument terminals can withstand the effects of a defibrillator discharge.

Liquid Spillage as per IEC 60601-2-2

The SuperPulse Generator enclosure will prevent reasonable amounts of liquid from interfering with the generator’s safe and satisfactory operation.

Intermittent operation — The SuperPulse Generator is cooled by natural convection. Under maximum power setting and rated load conditions the SuperPulse Generator will provide full power output with the minimum constraint of 10 seconds on, 30 seconds off, duty cycle for 1 hour.

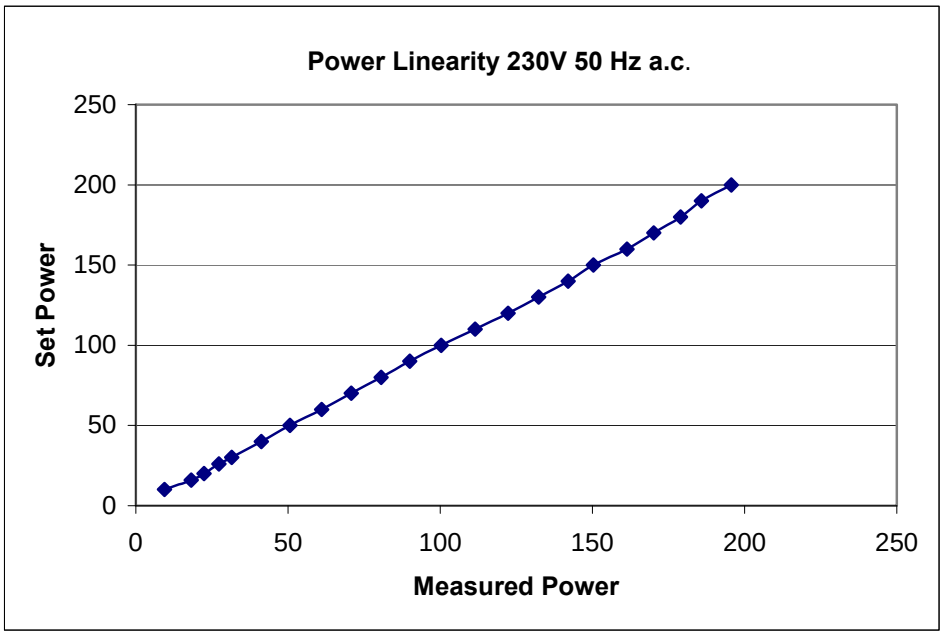
Output Waveform and Characteristics

Waveform — The RF output is a variable amplitude sinusoid waveform varying between approximately 340 kHz and 450 kHz, corresponding to minimum and maximum load impedance respectively.

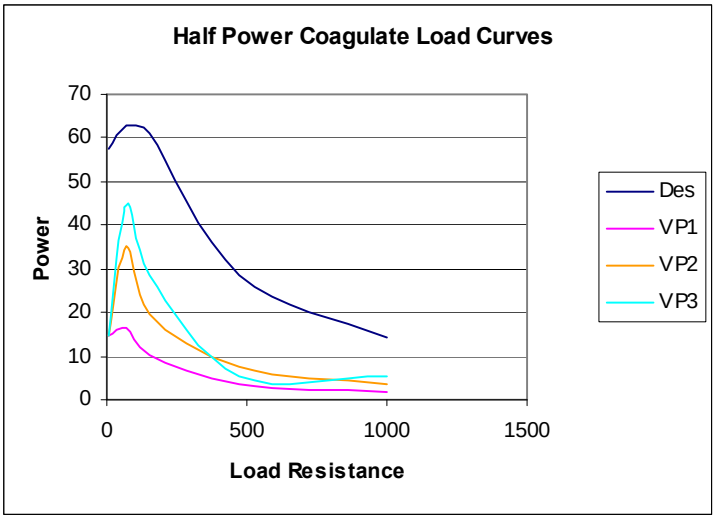
Crest Factor — A constant crest factor of 1.4 nominal for all outputs, except VP, TS, T and SP.

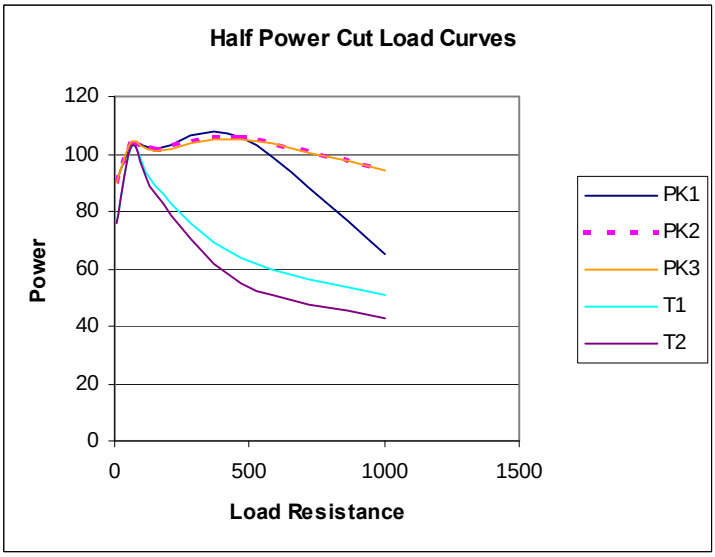
Power	Maximum power 200 watts into 400 ohms (PK).	
	Maximum power 320 watts into 150 ohms (SP1).	
	Maximum power 325 watts into 200 ohms (SP2).	
	Maximum power 333 watts into 200 ohms (SP3).	
	Maximum power 128 watts into 70 ohms (DES).	
Max Voltage	PK1/SP1	360 Volts Peak
	PK2/SP2/TS1/TS2	434 Volts Peak
	PK3/SP3	480 Volts Peak
	T1	434 Volts Peak
	T2	480 Volts Peak
	DES	170 Volts Peak
	VP1	103 Volts Peak
	VP2	141 Volts Peak
	VP3	170 Volts Peak
	TP1	360 Volts Peak
	TP2	397 Volts Peak
	TP3	434 Volts Peak

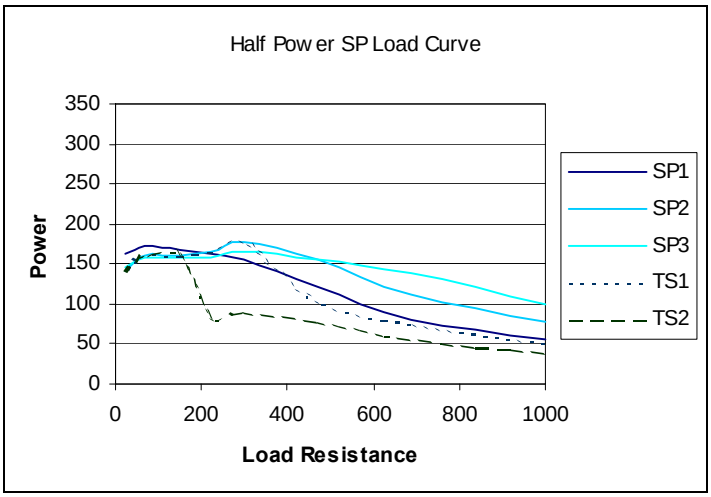
CAUTION The following load curves apply to the fundamental power delivery capability of the SuperPulse Generator alone. They do not imply a given power output for any given instrument and connector cable configuration when used with the SuperPulse Generator. Each accessory will self-impose an upper set power limit for the SuperPulse Generator.



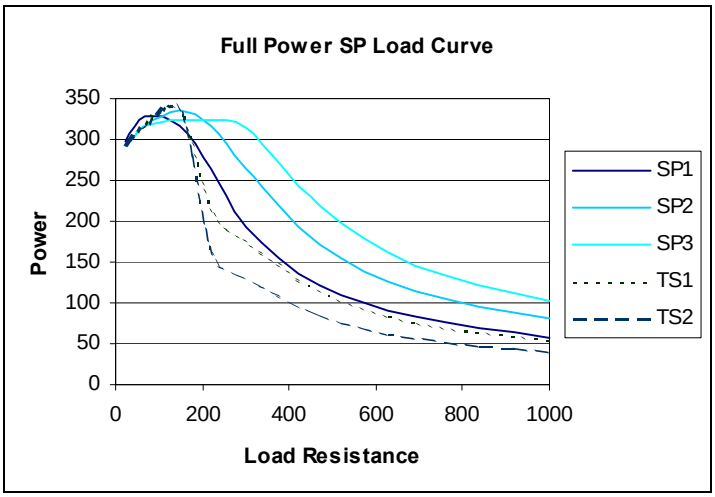
Linearity (PK3 into 150)

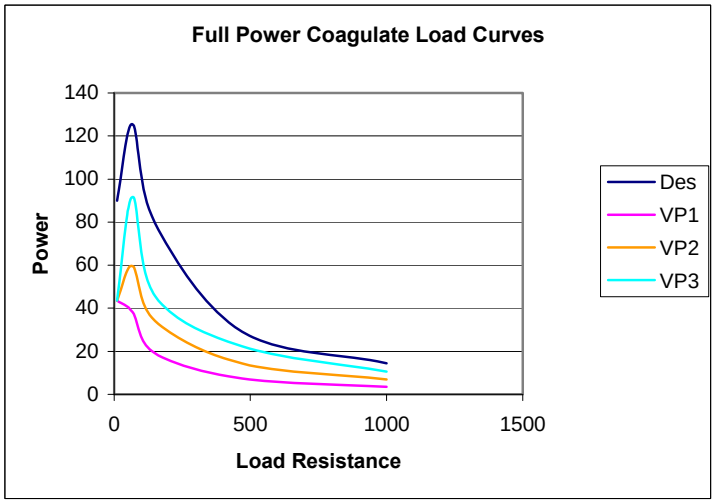


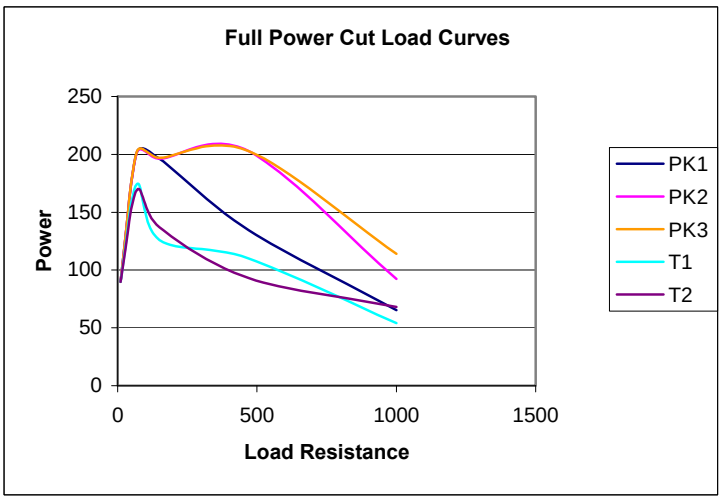




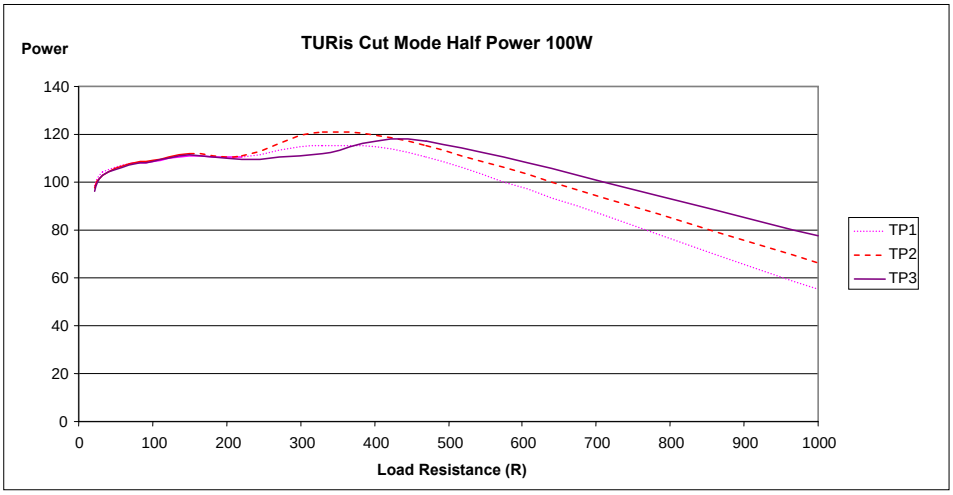
Half Power Load Curves

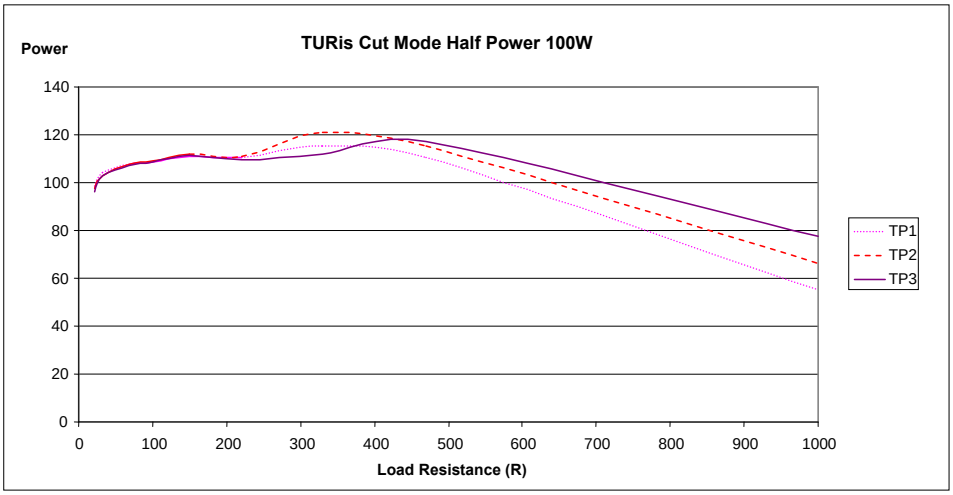






Full Power Load Curves





Vapor Pulse Waveforms, VP3, VP2 & VP1:

Pulsed coagulation outputs with a limited maximum output voltages. During the off periods, no RF output occurs. Repetition rates for each VP waveform will be constant but may vary with different instrument types.

Voltage limits:

VP3 - 120Vrms
VP2 - 100Vrms
VP1 - 73Vrms

The output power is defined as follows:

$$AveragePower = \frac{PeakPower \times OnTime}{CycleTime}$$

Where the Peak power is constant, the cycle time (the time for a complete on/off period) is preset and the On/Off ratio is varied dependent on set power.

SuperPulse waveforms, SP1, SP2, SP3:

Pulsed vaporization outputs, with limited maximum output voltages. During off periods no RF output occurs. Repetition rates will vary with impedance, above 330Ω giving continuous operation.

The output power for given load is defined as follows:

$$AveragePower = \frac{PeakPower \times OnTime}{CycleTime}$$

Where the Peak Power into a given load is constant and both the Cycle Time and the On Time varies dependent on set power and load impedance.

Fault and Error Symbol Interpretation

Most technical problems are indicated by either a fault or error symbol that appears in the Generator display window.

Three levels of failure reporting exist within the generator.

A “Soft” [S] Fault describes events bringing the attention of the user to an attempt to use the Generator outside the specification. This will be annunciated by a warning beep.

A “Recoverable” [R] Fault describes a condition that is a transient, non-hazardous event; recoverable using a Generator reset function. To reset the Generator after a fault occurs, first depress and release the Mode / Menu button once. The fault symbol on the display should flash. Depress and release the Mode / Menu button once more to complete the reset.

The symbol on the display will be of the form:

The symbol on the display will be of the form:

“FAULT CODE
X00 REF XX”

IMPORTANT *Remember to take note of the fault symbol for reporting to a service engineer before completing the reset.*

A “Fatal” [F] Error describes a failure that is not recoverable.

An error symbol is displayed as for the recoverable faults, except that it indicates that a service is required.

WARNING *An error symbol indicates an equipment malfunction, which may be hazardous. Disconnect all accessories and switch the Generator off. Switch the Generator back on and if the self-test is completed satisfactorily as evidenced by the “Attach PK Cable” symbol on the display, the failure occurred in the accessories which should be discarded and replaced. If the self-test fails, then all functions will be inhibited and no attempt should be made to use the generator. Contact the appropriate address located on the front of the manual for assistance.*

In the following list, where indicated as recoverable, this would be displayed as a fault symbol as described above.

ERROR CODE	REF	TEXT STRING	TYPE	DESCRIPTION
100	10	SYSTEM RESET	[R]	Software execution failure (watchdog reset)
100	11	INTERNAL FAILURE	[F]	ROM checksum failure
100	12	SETTINGS CORRUPT	[R]	Non volatile memory corrupt or not initialised
100	13	INTERNAL FAILURE	[F]	Program failure (unexpected value or state)
100	14	OUTPUT POWER FAIL	[R]	Power generation fault on start up (PK)
100	15	INTERNAL FAILURE	[F]	Power generation shutdown fault
100	16	OUTPUT POWER FAIL	[R]	Power generation fault on start up (SP)
100	17	SYSTEM RESET	[R]	Software execution failure
100	18	INTERNAL ERROR	[F]	Background loop timing

ERROR CODE	REF	TEXT STRING	TYPE	DESCRIPTION
100	19	INTERNAL ERROR	[F]	Continuous test timing
200	10	INTERNAL FAILURE	[F]	PWM signal: shorted high
200	11	INTERNAL FAILURE	[F]	PWM signal : shorted low
200	12	INTERNAL FAILURE	[F]	SYNC signal : shorted high
200	13	INTERNAL FAILURE	[F]	SYNC signal : shorted low
200	14	INTERNAL FAILURE	[F]	ENERGY signal : stuck high
200	15	INTERNAL FAILURE	[F]	IOUT signal: stuck high (comparator in)
200	16-17	Not used	---	**----**
200	18	INTERNAL FAILURE	[F]	CUT/COAG signal: stuck high
200	19	INTERNAL FAILURE	[F]	CUT/COAG signal: stuck low
200	20	INTERNAL FAILURE	[F]	CLAMP signal error (DAC output)
200	21	INTERNAL FAILURE	[F]	BOOST signal error (DAC output)
200	22	INTERNAL FAILURE	[F]	PEAKSET signal error (DAC output)
200	23	INTERNAL FAILURE	[F]	PEAK signal error: stuck high (comparator in)
200	24	INTERNAL FAILURE	[F]	RF_DET signal error: stuck low
200	25	INTERNAL FAILURE	[F]	OVERDOSE signal error: permanently ON
200	26	INTERNAL FAILURE	[F]	ENERGY signal error: stuck low
200	27	Not used	---	**----**
200	28	INTERNAL FAILURE	[S]	Temperature monitor inoperative
200	29	------	----	Reserved for audio fault detection
200	30	Not used	----	**-----**
200	31	INTERNAL FAILURE	[F]	CURRLIM signal error (DAC output)
200	32	INTERNAL FAILURE	[F]	VOLTLIM signal error (comparator input)
200	33	INTERNAL FAILURE	[F]	BUSVOLTS signal error (analogue input)
200	34	INTERNAL FAILURE	[F]	Incorrect PK RF board installed
200	35	INTERNAL FAILURE	[F]	RF relay 1 (socket) not operating
200	36	INTERNAL FAILURE	[F]	RF relay 2 (poles) not operating
200	37	INTERNAL FAILURE	[F]	SP board RF_ACTIVE stuck on
200	38	INTERNAL FAILURE	[F]	SP board Output relay non-functional
200	39	INTERNAL FAILURE	[F]	SP board BUS relay non-functional
200	40-2	Not used	---	-----
200	43	INTERNAL FAILURE	[F]	CPU POST failure
200	44	RAM	[R]	RAM test failure [POST check]
200	45	INTERNAL FAILURE	[F]	Crystal failure [POST check]
200	47	INTERNAL FAILURE	[F]	Analogue reference failure [POST check]
200	48	INTERNAL FAILURE	[F]	CLAMP_SET failure [POST check]
200	49	INTERNAL FAILURE	[F]	BOOST_SET failure [POST check]
200	50	INTERNAL FAILURE	[F]	CURRLIM_SET failure [POST check]
200	51	INTERNAL FAILURE	[F]	PEAK_SET failure [POST check]

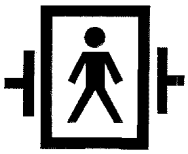
ERROR CODE	REF	TEXT STRING	TYPE	DESCRIPTION
200	52	INTERNAL FAILURE	[F]	COAG_CUT failure [POST check]
200	53	INTERNAL FAILURE	[F]	PK_CUT_COAG failure [POST check]
200	54	INTERNAL FAILURE	[F]	PK_SKT_SET failure [POST check]
200	55	INTERNAL FAILURE	[F]	SUPERPULSE_RELAY failure [POST check]
200	56	INTERNAL FAILURE	[F]	NO_RF failure [POST check]
200	65	INTERNAL FAILURE	[R]	RFBUS_VOLTS failure [POST check]
200	66	INTERNAL FAILURE	[R]	POST AUDIO Set-up [POST check]
200	67	INTERNAL FAILURE	[F]	PSU_STATUS failure [POST check]
200	68	INTERNAL FAILURE	[F]	Mains input failure [POST check]
200	69	INTERNAL FAILURE	[F]	OVERDOSE failure [POST check]
200	70	INTERNAL FAILURE	[F]	PWM low failure [POST check]
200	71	INTERNAL FAILURE	[F]	ID CAL circuit failure [POST check]
200	72	INTERNAL FAILURE	[F]	BUSLIM failure [POST check]
200	73	INTERNAL FAILURE	[F]	CURRLIM failure [POST check]
200	74	INTERNAL FAILURE	[F]	VOLTLIM failure [POST check]
200	75	INTERNAL FAILURE	[F]	SPRF_ACTIVE failure [POST check]
200	76	INTERNAL FAILURE	[F]	VCC_ANA_DIV_2 failure [POST check]
200	77	INTERNAL FAILURE	[F]	12V failure [POST check]
200	78	INTERNAL FAILURE	[F]	0V failure [POST check]
200	80	INTERNAL FAILURE	[F]	RF_VOLTAGE [POST check]
200	81	INTERNAL FAILURE	[F]	RF_CURRENT failure [POST check]
200	82	INTERNAL FAILURE	[F]	ANALOGUE_REF failure
200	83	INTERNAL FAILURE	[F]	VCC_ANA_DIV_2 failure
200	84	INTERNAL FAILURE	[F]	12V failure
200	85	INTERNAL FAILURE	[F]	0V failure
200	86	INTERNAL FAILURE	[F]	RF_DET stuck high failure
200	87	INTERNAL FAILURE	[F]	PSU_STATUS failure
200	88	INTERNAL FAILURE	[F]	Mains input failure
200	89	INTERNAL FAILURE	[F]	BUSLIM failure
200	90	INTERNAL FAILURE	[F]	CURRLIM_SET failure
200	91	INTERNAL FAILURE	[F]	SP_PSU_OR_PK_RELAY failure
200	92	INTERNAL FAILURE	[F]	Electrode ID Failure
300	10	THERMAL SHUTDOWN	[R]	Internal overheating
300	11	INTERNAL FAILURE	[F]	Excess RF input voltage error (RFBUS > set)
300	12-13	Not used	---	**-----**
300	14	OUTPUT SHORTED	[R]	Excessive RF output
300	15	INTERNAL ERROR	[F]	Impedance V, I feedback circuit error
300	16	INTERNAL ERROR	[R]	SP board not supplying RF energy
300	17-19	Reserved		

ERROR CODE	REF	TEXT STRING	TYPE	DESCRIPTION
300	20	INVALID ELECTRODE	[SOFT]	Unsupported electrode type
300	21	SP OUTPUT ERROR	[R]	Persistent over voltage or current error
400	10	FOOTPEDAL STUCK	[S]	Footswitch BLUE pedal stuck
400	11	FOOTPEDAL STUCK	[S]	Footswitch YELLOW pedal stuck
400	12	FOOTPEDAL STUCK	[S]	Black Mode Footswitch stuck
400	14	INTERNAL FAILURE	[F]	Electrode identification circuit fault
400	15	BUTTON STUCK	[R]	Front panel: CUT (left) UP button stuck
400	16	BUTTON STUCK	[R]	Front panel: CUT (left) DOWN button stuck
400	17	BUTTON STUCK	[R]	Front panel: blue UP button stuck
400	18	BUTTON STUCK	[R]	Front panel: blue DOWN button stuck
400	19	BUTTON STUCK	[R]	Front panel: MODE / MENU button stuck
400	20	BUTTON STUCK	[R]	Front panel: STANDBY button stuck
400	21	FOOTPEDAL STUCK	[R]	Footswitch pedal state indeterminate
400	26	CHECK IRRIGANT/ELECTRODE	[S]	Generated if a TURis electrode is attached and activated without a saline solution being present, or there is an electrode connection fault.
400	30	Not used	---	----
500	10	SERIAL COMMS	[R]	Serial port error

**To report an accessory failure, contact the appropriate address located on the front of the manual for assistance.

Red Warning Symbol
Attention, consult accompanying documents

This equipment intentionally emits RF energy during activation



This equipment provides a degree of protection against electric shock to TYPE B as defined in IEC60601-1. This equipment has an F type applied part capable of withstanding the effects of defibrillator discharge

This symbol indicates the conductor that may be used to provide potential equalization between the equipment and the installation busbar.

This symbol indicates the receptacle to which the generator footswitch should be attached.

Waste electrical and electronic equipment (WEEE)

Storage Conditions

	Represents the quantity of devices inside the package. # -Numeral corresponds to the number of devices inside the package and must be present inside the diamond icon.
QTY	Represents the quantity of salable units inside the package.
Manufactured for:	When a product is manufactured for Gyrus ACMI.
Rx only	CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a Physician or Dentist.

SECTION 13 PERIODIC EQUIPMENT SAFETY CHECKS

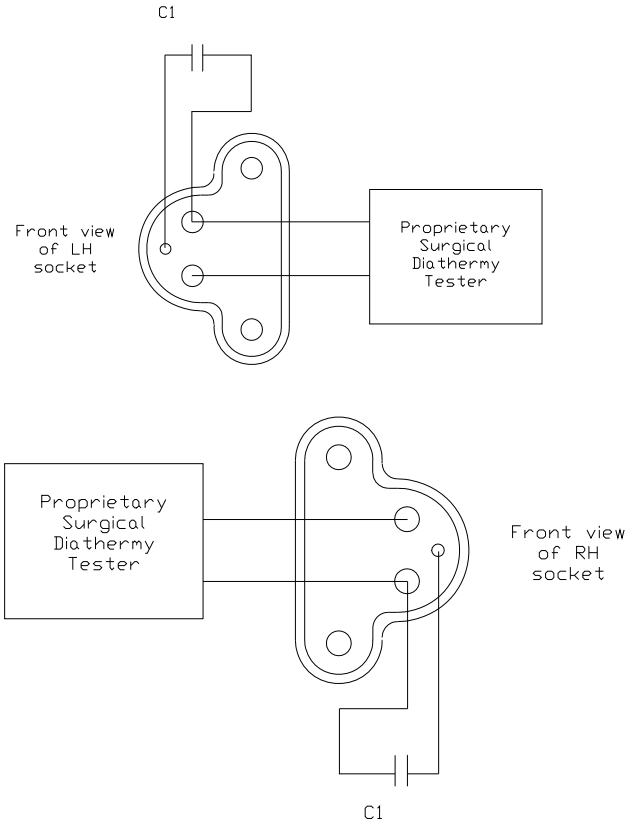
The manufacturer recommends that the Generator and Footswitch should be regularly inspected to ensure continued safety of operation throughout its service life. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge and practical experience to perform such tests.

NOTE: *There are no user serviceable items within the generator.*

- Inspect the Generator and the Footswitch for obvious signs of mechanical damage or wear. Ensure that the Generator case shows no sign of tampering. There are no user serviceable items within the Generator or Footswitch.
- Check that the Generator back panel label is present and decipherable and that the front panel markings and symbols are still legible.
- Retract the fuse drawer of the mains inlet connector and verify that both fuses are intact and match the rated current and breaking characteristics as per the back panel label.
- Verify that the resistance between the earth terminal of the mains inlet connector and the Generator enclosure is within the limits defined in EN 60601-1 or the corresponding national standard as applicable.
- Switch on the Generator, ensuring that the initial internal self-test is completed normally, as reported on the front panel display. Check that the audio alarm, front panel warning indicator and vacuum fluorescent display are functioning normally via the user verification sequence which follows initialization. Check Desiccation detector operation.
- Check that the enclosure earth leakage current is within the limits for Class I equipment as prescribed within EN 60601-1 or the corresponding national standard as appropriate.
- Measure the patient earth leakage currents and ensure it is within the limits of BF type equipment as defined within EN 60601-1 or a corresponding national standard.
- If there is any doubt about the PK RF output power of the generator, it must be returned to the supplier for testing. A power output assessment may be performed on the bipolar output by using the connections described below. The output may be compared to the load curves specified in the previous sections. The output should be within ±20% of the relevant curve. The diathermy tester must be rated to read Watts at the appropriate frequency and have non-reactive loads. All connections should be insulated wherever possible to prevent electric shock risk and short-circuiting. The generator sockets receive two and four millimetre diameter plugs.

  To measure desiccate outputs up to 150 Watts C1 shall be 4.7 nF +/- 1%. A 150 ohm load should be used.

  To measure PK outputs up to 200W C1 shall be 68nF +/-10%. A 150 ohm load should be used.
  It is difficult to measure the output of the SuperPulse and TS waveforms accurately whilst pulsing without the use of specialized equipment. It is, however, possible to measure the output in continuous wave mode by attaching a 560ohm load resistor. The value of C1 should be 4.7nF. The power should be set to 200W SP2 on the generator and the cut pedal pressed to produce an output.



- Details of these tests should be recorded in an equipment log with the date of test for future reference. Contact the service repair centre selected by the manufacturer, should a unit fault be suspected.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The SuperPulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the SuperPulse Generator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The SuperPulse Generator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The SuperPulse Generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The SuperPulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the SuperPulse Generator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input / Output Lines	±2 kV for Power Supply Lines ±1 kV for Input / Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential Mode ±2 kV Common Mode	±1 kV Differential Mode ±2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5 % U_T (>95 % Dip in U_T) for 0.5 Cycle 40 % U_T (60 % Dip in U_T) for 5 Cycle 70 % U_T (30 % Dip in U_T) for 25 Cycle <5 % U_T (>95 % Dip in U_T) for 5 sec	<5 % U_T (>95 % Dip in U_T) for 0, 5 Cycle 40 % U_T (60 % Dip in U_T) for 5 Cycle 70 % U_T (30 % Dip in U_T) for 25 Cycle <5 % U_T (>95 % Dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SuperPulse Generator requires continued operation during power mains interruptions, it is recommended that the SuperPulse Generator be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The SuperPulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the SuperPulse Generator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 Vrms 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SuperPulse Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = [1.17]\sqrt{P}$ $d = [1.17]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.33]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an elctromagnetic site survey should be considered. If the measured field strength in the location in which the SuperPulse Generator is used exceeds the applicable RF compliance level above, the SuperPulse Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SuperPulse Generator. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the SuperPulse Generator

The SuperPulse Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SuperPulse Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SuperPulse Generator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter **W**	**Separation Distance According to Frequency of Transmitter** **m**		
	150 kHz to 80 MHz $d = [3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3.5/E_1]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [7/E_1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SECTION 15 LIMITED WARRANTY

The manufacturer warrants the products listed below to be free from defects in material and workmanship under normal use and service for the period(s) set forth below. The manufacturer's obligation under this warranty is limited to the repair or replacement, at its sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to the manufacturer's satisfaction, that the product is defective. This warranty does not apply to any product, or part thereof, which has been repaired or altered outside the manufacturer's factory in a way so as, in the manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect or accident.

The warranty periods for the components of the PlasmaKinetic™ SuperPulse Generator are as follows:

Component	**Warranty Period**
Generator and footswitch	One year from shipment date

This warranty is in lieu of all other warranties, expressed or implied, including, without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of the manufacturer. The manufacturer neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of the manufacturer's products. Notwithstanding any other provision herein or in any other document or communication. The manufacturer's liability with respect to this agreement and products sold hereunder shall be limited to the aggregate purchase price for the goods sold by the manufacturer to the customer. There are no warranties which extend beyond the terms hereof. The manufacturer disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

The manufacturer reserves the right to make changes in equipment built and/or sold by it at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

The products listed above are manufactured in the United Kingdom:

Manufactured For:

Gyrus ACMI, Inc.
136 Turnpike Road
Southborough
MA 01772-2104
USA

Customer Service USA:

Customer Service: 1-888-524-7266
Technical Service: 1-800-621-3739
www.gyrusacmi.com

EC REP

Gyrus Medical Ltd.
Fortran Road
St Mellons
Cardiff
CF3 0LT
United Kingdom

CE 0344

PlasmaKinetic™ PK Plasma-Cise™, PK Plasma-Cut™ and PK SEAL® are trademarks or registered trademarks of Gyrus ACMI, Inc., and/or its affiliated entities, in the U.S. and/or other countries.

Rx only - CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician

NOTE **THE UL APPROVAL APPLIES TO GYRUS ACMI PRODUCTS ONLY**

MEDICAL ELECTRICAL EQUIPMENT
CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRIC SHOCK, FIRE, MECHANICAL
HAZARDS AND OTHER SPECIFIED HAZARDS ONLY IN
ACCORDANCE WITH UL60601-1 AND CAN/CSA C22.2 NUMBER 601.1

21FA

E176665

CAUTION	USE ONLY THE POWER CORD PROVIDED BY YOUR PRODUCT SUPPLIER. DO NOT USE ANY OTHER POWER SUPPLY CORD.	**MISE EN GARDE**	UTILISER UNIQUEMENT LE CORDON D'ALIMENTATION FOURNI PAR VOTRE FOURNISSEUR. NE PAS UTILISER D'AUTRE TYPE DE CORDON D'ALIMENTATION.
CAUTION	THE POWER SUPPLY CORD PROVIDED IS INTENDED FOR NORTH AMERICAN 110V USE. THIS POWER CORD IS UL LISTED. TYPE SJT, RATED 120V AT 10A MINIMUM. FOR OPERATION AT OTHER MAINS SUPPLY VOLTAGES CONSULT YOUR LOCAL PRODUCT REPRESENTATIVE FOR ADVICE OR THE PROVISION OF A REPLACEMENT POWER CORD.	**MISE EN GARDE**	LE CORDON D'ALIMENTATION EST CONCU POUR UNE UTILISATION EN AMERIQUE DU NORD SOUS UNE TENSION DE 110V. CE CORDON D'ALIMENTATION EST DE TYPE UL, SJT. ALIMENTATION 120V ET 10A MINIMUM. CONTACTER VOTRE REPRESENTANT LOCAL POUR UNE UTILISATION A UN AUTRE VOLAGE.
WARNING	RISK OF FIRE REPLACE FUSE AS MARKED	**ATTENTION**	RISQUE D'INCENDIE REMPLACER LE FUSIBLE COMME INDIQUE